

Report to the Legislature

Recommendations for Home-Generated Pharmaceutical Collection Programs in California



California Department of Resources Recycling and Recovery

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Executive Summary

Pharmaceutical wastes are a societal problem because they show up in the environment, particularly in our precious waterways, and because some are “controlled substances” that can be illegally diverted and abused. Accidental prescription overdoses, teen and adult abuse of prescription drugs, along with impacts to surface waters and groundwater when drugs are flushed down the toilet, all highlight the need for safe pharmaceutical waste collection programs.

Enacted in 2007, Senate Bill 966 (Simitian, Chapter 542, Statutes of 2007) addresses improper disposal of pharmaceutical waste. In addition to tasking the California Department of Resources Recycling and Recovery (CalRecycle) with establishing criteria and procedures for model pharmaceutical collection programs, the department was also charged with preparing this report. The report evaluates California’s current pharmaceutical waste collection programs and provides recommendations to the Legislature for the potential implementation of a statewide program and statutory changes.

Based on the analysis described in detail in this report, CalRecycle recommends that the Legislature adopt a combination of two options related to pharmaceutical waste collection programs: 1) statutory changes to establish clear state roles and responsibilities, provide direction to resolve several implementation challenges, and direct that the [*Criteria and Procedures for Model Home-Generated Pharmaceutical Waste Collection and Disposal Programs*](#)¹ (Model Guidelines) be refined and converted into regulations; and 2) statutory direction to address funding barriers by providing financing through a private sector approach with government oversight, commonly referred to as product stewardship.

SB 966 was a major step forward in development of a consistent approach to handle home-generated pharmaceutical wastes. The law directed CalRecycle, working with several other state, local, and federal agencies, to: 1) establish criteria and procedures for model collection programs for home-generated pharmaceutical waste; 2) evaluate the model programs for efficacy, safety, statewide accessibility, and cost-effectiveness; 3) consider the incidence, if any, of diversion of drugs for unlawful sale and use; and 4) provide the Legislature with recommendations for statutory changes and the potential implementation of a statewide program.

After numerous meetings with state agencies and stakeholders, in February 2009 CalRecycle adopted voluntary Model Guidelines. CalRecycle then surveyed collection programs around the state, some of which were in existence prior to this time, to see whether they met the voluntary Model Guidelines, and conducted additional stakeholder meetings and a workshop in 2010 to discuss survey findings and potential options.

CalRecycle found that only about one-third of existing programs in California meet the voluntary Model Guidelines. Of the major types of programs (law enforcement collection, pharmacy collection, household hazardous waste collection, periodic collection “events,” and mail-back programs), each has advantages and barriers in being able to meet the voluntary Model Guidelines. For example, law enforcement programs can readily meet requirements for collecting controlled substances, but the public may not be willing to bring pharmaceutical wastes to police stations. Further, law enforcement agencies themselves have higher resource allocation priorities. Pharmacies are widespread and accessible, but they typically do not meet all of the safety protocols (e.g., regarding collection bins and security) delineated in the voluntary Model Guidelines. Household Hazardous Waste facilities also face similar issues as pharmacies, particularly relative to safety, and are dependent on local government funding support. Periodic collection

events are somewhat easier to implement for local governments and can accommodate large amounts of materials in a short time, but are not as cost-effective as continuous collection programs, often do not have safety protocols, and are subject to local government budgetary constraints. Mail-back programs can be convenient and safety is not a major concern, but there are only three such programs in the state and a high return rate is necessary for the method to be cost-effective.

Several key barriers have made the voluntary Model Guidelines difficult to meet:

- Federal law. The federal Controlled Substances Act requires strict protocols for the collection of controlled substances to prevent their illegal diversion and abuse. Although controlled substances represent only about 10 percent of home-generated pharmaceutical wastes, the requirements for their safe management (e.g., requiring only law enforcement officials to handle them) means most collection programs are costly. CalRecycle is not aware of similar requirements in other countries with pharmaceutical collection programs. The Controlled Substances Act has been amended by the *Secure and Responsible Drug Disposal Act of 2010* (United States Senate, S. 3397, 111th Congress), which should make it easier to collect controlled substances once implementing regulations are promulgated.
- California's complicated statutory and regulatory framework. There is no clear statutory definition of home-generated pharmaceutical wastes, nor is there an identified agency or department that has sole or ultimate authority for home-generated pharmaceutical waste collection, consolidation, management, and disposal. Instead, the federal Drug Enforcement Administration and several California state agencies (Department of Public Health, Board of Pharmacy, and Department of Toxic Substances Control) exercise varying degrees of authority or policies, making it challenging for local jurisdictions to develop and maintain effective collection and management programs they know conform to legal requirements. These conflicting authorities and policies are manifested in the Model Guidelines in the form of safety requirements included to satisfy differing agency requirements and policies but are costly to implement and caused some stakeholders to feel they were unnecessary (e.g., two-key locking collection bins in pharmacies, use of secure containers at household hazardous waste sites, and registered haulers).
- Lack of funding. Based on survey results, CalRecycle found that local governments currently fund more than 80 percent of collection programs and pharmacies fund another 15 percent. CalRecycle is not aware of funding support from pharmaceutical manufacturers for collection programs in California; this contrasts significantly with the level of private sector funding in Canada and several European countries.

Based on these findings and to meet the key tenets of SB 966, in particular to provide convenient collection opportunities for home-generated pharmaceutical wastes, CalRecycle considered four options, which are described in detail in Section V. CalRecycle recommends the Legislature adopt a combination of two options:

- “Establish Clear State Agency Roles and Responsibilities, Improve Model Guidelines and Enforcement, and Convert Guidelines to Regulation” (Option 2) and
- “Implement Product Stewardship” (Option 3)

Option 2 would entail statutory changes to establish clear state roles and responsibilities, provide direction to resolve several implementation challenges, and direct that the Model Guidelines be refined and converted into state regulations. Option 3 would address the key funding barrier by providing program

financing through a private sector approach with government oversight, commonly referred to as product stewardship. Manufacturers or drug brand owners would design, manage, and finance a statewide program, while state government would oversee program implementation and enforcement.

Implementing these two options, each of which is described in detail in Section V, would address key barriers and provide for a sustainable system of collection programs by:

- Providing clear state agency roles and responsibilities;
- Clearly defining home-generated pharmaceutical wastes, consolidated home-generated pharmaceutical wastes, and acceptable management practices;
- Supporting safe collection, transport and management of home-generated pharmaceuticals;
- Offering flexibility and allowing multiple types of collection systems;
- Providing sustainable program funding; and
- Encouraging cost-efficiency

Since regulating controlled substances is under federal authority, fully instituting these two options to allow for cost-effective collection programs will not be totally feasible until regulations are in place to implement the newly signed [*Secure and Responsible Drug Disposal Act of 2010*](#). In addition, these two options would likely take at least a few years to implement (i.e., to enact state legislation and develop the required regulations and stewardship program), yet unwanted drugs need to be removed from households now. For this reason, the Legislature may also wish to consider that in the short-term, public safety may be best served by encouraging landfill disposal options in communities where no other options currently exist. For example, Option 1 (i.e., promote use of the California Model Guidelines for existing collection programs and use of the federal guidelines regarding proper disposal where collection programs do not exist) could be implemented as a short-term solution, while efforts to implement Options 2 and 3 proceed. While this option would not address existing statutory and regulatory barriers or address the lack of funding for sustainable collection programs, as an interim measure it would provide for convenient, low-cost disposal, would not require new legislation, and would support some key tenets of SB 966.

I. Introduction

1. *Senate Bill 966 (SB 966)*

Enacted in 2007, Senate Bill 966 (Simitian, Chapter 542, Statutes of 2007) addresses improper disposal of pharmaceutical waste into sewer systems, which results in pharmaceuticals entering waterways and drinking water. The goal of SB 966 is to establish a program through which the public may conveniently return drugs for safe and environmentally sound disposal.

SB 966 directed the California Integrated Waste Management Board, which is now the California Department of Resources Recycling and Recovery (CalRecycle), to:

1. Establish criteria and procedures for model collection programs, by December 2008

CalRecycle worked closely with numerous agencies, including the California Department of Public Health (CDPH), the Department of Toxic Substances Control (DTSC), the State Water Resources Control Board (SWRCB), and the California State Board of Pharmacy (CBOP), and considered stakeholder input to develop criteria and procedures for model pharmaceutical waste collection programs. CalRecycle adopted Model Guidelines in November 2008, with a subsequent revision in February 2009. Programs are not required to follow these Model Guidelines but they must be consistent with them in order to be considered a model program under SB 966.

2. Evaluate model collection programs in California

CalRecycle sent surveys to all known programs that collect home-generated pharmaceuticals in California. This report presents the results of these surveys.

3. Report to the Legislature, by December 2010

As required by SB 966, CalRecycle prepared this report to include the following components:

- An evaluation of the model programs for efficacy, safety, statewide accessibility, and cost effectiveness;
- Consideration of the incidence of diversion of drugs for unlawful sale and use, if any; and
- Recommendations for the potential implementation of a statewide program and statutory changes.

2. *Purpose of Legislative Report*

The main purpose of this report is to offer recommendations to the Legislature on options for implementing a statewide collection program for home-generated pharmaceuticals, as directed in SB 966 (Public Resources Code Sections 47120 Et Seq.).

To develop recommendations, CalRecycle reviewed laws and policies that impact collection programs, analyzed collection programs elsewhere in the world and in other states, evaluated collection programs in California, in particular those that are consistent with the Model Guidelines, and considered comments from stakeholders and affected parties after this information was presented in a July 20, 2010 workshop.

This report includes the following sections:

- **Overview of Programs Outside of California (Section II):** Covers a range of programs in other countries and states;
- **Challenges and Barriers (Section III):** Outlines some of the challenges to program implementation;
- **Program Surveys and Results (Section IV):** Identifies the types and number of home-generated pharmaceutical waste collection programs in California, the number that meet the Model Guidelines for model programs within each type, and an evaluation of programs based on the four factors in SB 966 (safety, statewide accessibility, cost-effectiveness, and efficacy); and
- **Potential Options and Recommendations for Further State Action (Section V):** Discusses potential options for state action along with recommendations.

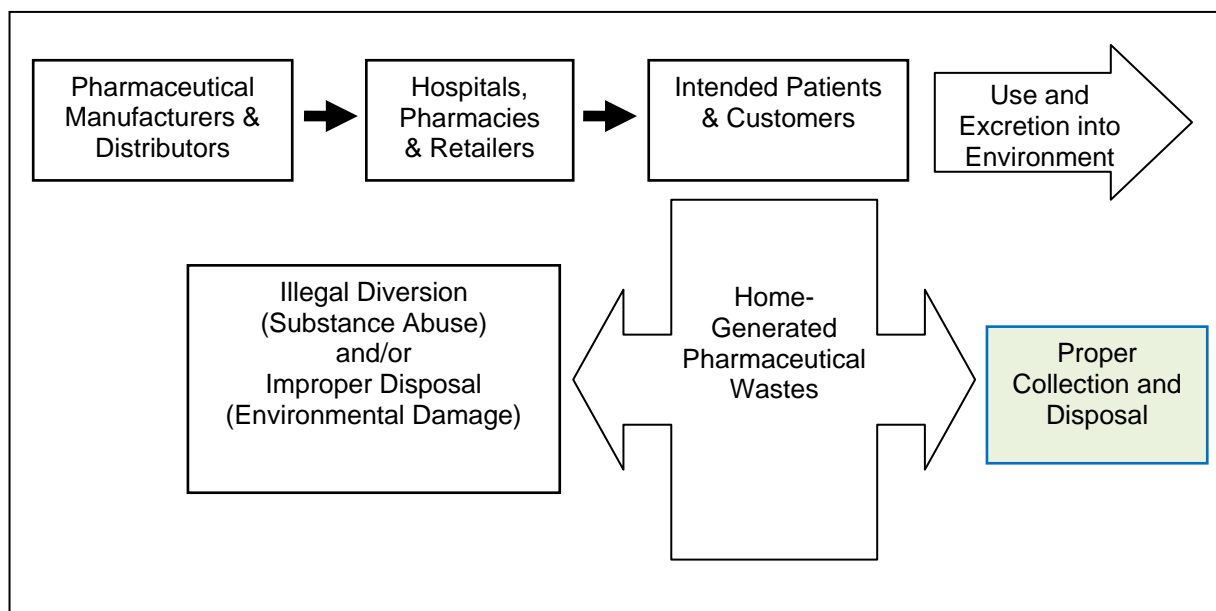
Several topics not within the direct scope of this analysis but related to the topic are listed below. While some topics are discussed when necessary as they relate to the collection programs, the report does not discuss all topics in detail:

- Excretion. While human excretion is a major pathway for pharmaceuticals to reach the environment, it is a separate problem from unused pharmaceuticals that become home-generated waste. The latter issue, home-generated waste, is the focus of this report.
- Drug Distribution Solutions. While fewer prescriptions, reduced sales of pharmaceuticals, or changes resulting in more complete usage of medications could result in a lower amount of home-generated pharmaceuticals, these actions would occur before pharmaceuticals become home-generated waste.
- Controlled Substances. SB 966 specifically states that it does not apply to controlled substances; however, they are mentioned in this report because their special requirements impact collection programs for other home-generated pharmaceutical wastes.
- Reverse Distributors. Reverse distributors collect unused and expired medication from hospitals and pharmacies and in return provide monetary credit or disposal of that waste. This activity occurs before pharmaceuticals become home-generated waste. In addition, several concerns exist regarding applying this concept to home-generated wastes.*

Figure 1 shows a simplified view of the flow of pharmaceuticals, including both prescription medications and non-prescription (over-the-counter) medications.

* Once dispensed, medications may be tampered with, kept in inappropriate conditions, and become unfit for redistribution. According to the California Board of Pharmacy, a reverse distributor may not accept previously dispensed medicine and may not have sufficient safety standards to prevent illegal drug diversion.

Figure 1. Simplified Flow of Pharmaceuticals



This report only deals with one aspect of the life cycle of pharmaceuticals, specifically the post-consumer fate of unused pharmaceuticals that become home-generated pharmaceutical waste. This report discusses current efforts and future options to properly collect and dispose of this home-generated pharmaceutical waste in ways that minimize illegal diversion (potentially leading to substance abuse) and improper disposal (potentially leading to environmental damage).

3. Home-Generated Pharmaceuticals in California

Based on information available to CalRecycle, collection programs in California collect approximately 200,000 pounds of home-generated pharmaceutical waste per year. These collection programs appear to be quite safe with very low illegal diversion. Out of 256 collection sites or programs representing 86 percent of all known programs operating in California, a CalRecycle survey found that in the past 15 years there were no reported signs of illegal drug diversion (see Section III, *1. High Cost of Safe Collection*).

However, these programs likely collect a small percentage of all home-generated pharmaceutical waste, although there is not a definitive estimate of the amount of home-generated pharmaceutical waste in the state. Several sources suggest that a very large amount is sold and that a significant percentage subsequently becomes waste in California:

- In California pharmacies, the total retail sales for filled prescription drugs in 2009 (not including over-the-counter drugs or mail order prescriptions) reached nearly \$19 billion for more than 300 million prescriptions.²
- The Associated Press estimated that Americans generate at least 250 million pounds of pharmaceuticals and contaminated packaging in medical facilities each year.³ Relative to California population, that would be approximately 30 million pounds in California hospitals alone.

- Some estimates suggest that 10 percent to 33 percent of all pharmaceuticals go unused.⁴ There is not universal agreement on these percentages, with some studies reporting as little as 3 percent unused while others report that 50 percent or more are unused.⁵
- In addition, the number of prescriptions per 100 people has increased between 1995 and 2008 from 0.8 to 1.2 nationwide.⁶ Considering our aging population, this trend is likely to continue.

Meanwhile, there is growing concern about illegal diversion of pharmaceuticals from homes. Collection programs provide a safe, legal, and environmentally preferable means to managing unwanted drugs from residences where they can be abused. This is a driving force for establishing home-generated pharmaceutical collection programs.

4. Current Status of Regulations, Statutes and Policy

In California, current statutory and regulatory authority to govern collection and disposal of home-generated pharmaceutical waste is divided amongst several state and federal entities. This division leads to confusing roles, responsibilities and program requirements, and is an underlying issue that challenges collection program administrators. For example:

- The U.S. Drug Enforcement Administration (DEA) governs the collection and disposal of controlled substances, a subset of home-generated pharmaceuticals, which requires law enforcement to oversee these activities;
- The California Board of Pharmacy (CBOP) licenses pharmacies, but currently does not explicitly authorize pharmacies to accept the return of home-generated pharmaceuticals, yet it supports Model Guidelines that allow collection following certain practices;
- The California Department of Toxic Substances Control (DTSC) regulates hazardous waste, which may include some pharmaceutical waste, while exempting home-generated pharmaceutical waste from classification as hazardous waste;
- The California Department of Public Health (CDPH), through the Medical Waste Management Act (MWMA), regulates collection and disposal of medical waste in California. However, it does not have statutory authority to regulate collection and disposal of home-generated pharmaceutical waste, which is excluded from the definition of medical waste. Instead, it applies a best management policy for collecting this waste. CDPH interprets this policy as follows: if home-generated pharmaceutical waste is consolidated with other home-generated pharmaceutical waste from different residences or is handled by a third party, then it is no longer considered home-generated but rather consolidated medical waste and the MWMA regulations apply, requiring the waste to be handled as medical waste.

Many stakeholders identified possible alternatives for revising the current statutes, regulations and policies to address confusion about roles and responsibilities and facilitate new take-back programs. These are explored in Appendix A: *Recommended Stakeholder Changes to Legislation, Regulations and Policies*, which contains a matrix of the current statutes, regulations and policies overseeing management of home-generated pharmaceuticals. It should be noted there is no consensus among stakeholders on roles and responsibilities and without clear legislative direction and state agency authority over certain tasks, confusion will continue.

II. Overview of Programs Outside of California

Other countries and states face similar challenges with managing unwanted pharmaceuticals. CalRecycle found examples of pharmaceutical collection programs in a number of other countries and states and analyzed them for their approach, costs, and effectiveness, where information was available.

Below are several programs that stand out for reasons noted. Much of the information on programs outside of the United States comes from the Health Canada report, [*Pharmaceutical Disposal Programs for the Public: A Canadian Perspective*](#),⁷ which serves as a reference for readers seeking more detailed information.

Basic information about many of these international and state programs is captured in the table in Appendix B: [*Overview of Pharmaceutical Collection Programs Outside of California*](#).⁸ While the descriptions below include cost information as it is reported, cost comparisons should not be used to draw firm conclusions about programs because data may compare different program attributes. This is a common problem that arises when comparing programs, especially across countries. CalRecycle still included the information as it is the best information available to suggest expected costs and encourage efforts to establish common metrics.

CalRecycle observed some common themes among the programs researched. All programs reviewed seek to provide a secure system for pharmaceuticals and programs in other countries use pharmacies as collection points. It appears that other countries do not have laws on par with the U.S. Controlled Substance Act, which only allows law enforcement officials to handle controlled substances (e.g., narcotics). This means that outside of the United States, pharmacies can serve as convenient consumer drop-off locations for all types of pharmaceuticals. This may change once regulations are promulgated as part of the recently passed *Secure and Responsible Drug Disposal Act of 2010*, (also see Section II, 2. *National Programs*, Federal Legislation and Regulations below). Also, most countries with collection programs have significant industry participation, including at least some industry funding, with the exception of Sweden, which operates collection through nonprofit, state-run pharmacies. Additionally, Australia has a primarily government-funded program.

When the private sector funds and manages collection and safe disposal of drugs, such a program is referred to as a product stewardship program. Product stewardship programs offer a private sector approach to waste management. Appendix B offers cost information on various pharmaceutical programs and this preliminary information suggests a generally lower cost per capita for those programs with greater industry funding. Overall, however, CalRecycle is not able to draw any specific conclusions about which of these programs are most effective due to data gaps and a lack of detailed information about the programs to ensure a fair comparison.

1. International Guidelines and Programs

WORLD HEALTH ORGANIZATION

- The **World Health Organization**⁹ issues guidelines for pharmaceuticals management during and after emergencies. These guidelines state that if take-back programs are not available and pharmaceuticals

are treated prior to disposal by waste immobilization, it is acceptable to dispose of controlled substances in engineered or permitted landfills.¹⁰ Immobilization refers to either encapsulation or inertization (removing the packaging materials from the pharmaceuticals, grinding pharmaceuticals, and mixing them with water, cement, and lime).

AUSTRALIA

- **Australia: Return Unwanted Medicines Project.** This national program allows consumers to return pharmaceuticals to any pharmacy across Australia. Most costs are covered by the Department of Health and Aging with limited support from the pharmaceutical industry. Preliminary information on costs per capita suggest the project is on par with other international programs, however it has a fairly low per capita collection rate in comparison. This program collects and makes available information on commonly returned medicines, reasons for return, and conducts targeted education campaigns. Consumers do not have to distinguish which drugs are controlled substances because pharmacies accept all types and then pharmacies follow specific disposal instructions for controlled substances or “Schedule 8 medicines.” The protocols for pharmacies, which must use approved collection bins, are available online at www.returnmed.com.au/.

EUROPEAN UNION

The European Union Directive 2004/27/EC, Article 127b requires that, “Member States shall ensure that appropriate collection systems are in place for medicinal products that are unused or have expired.”[†] As a result, numerous programs exist and several have data available as indicated below.[†] Additionally, Article 54j of this same directive has labeling requirements so information about collection programs appears on pharmaceutical packaging.

- **France: Cyclamed Program.** This national program allows consumers to return pharmaceuticals to local pharmacies for safe disposal. The program is funded and managed by the private sector (industry, pharmacies, and wholesalers). It stands out for having relatively high per capita collection and participation rates as noted in Appendix B. Also, the amount of pharmaceuticals collected, reported in terms of with and without packaging, indicates that it is very important to understand the extent to which packaging is included in measurements as it can significantly impact the collection rates. This program offers more information on its performance than many other programs.
- **Portugal: Valormed Program.** This national program allows consumers to return unused pharmaceuticals to local pharmacies for safe disposal. It is funded by members of pharmaceutical associations, including local pharmacies, manufacturers, distributors and chemical and pharmaceutical importers. This particular product stewardship program places an eco-fee of one cent on each package placed in the market. The program stands out as having a fairly high per capita collection as compared

[†] The report, *Pharmaceuticals in the environment — Result of an EEA workshop*, 2009 (available: www.eea.europa.eu/publications/pharmaceuticals-in-the-environment-result-of-an-eea-workshop) includes a summary of European programs and says the return rate in Switzerland is very high, followed by Ireland, Luxembourg, Sweden, and France. However, the report does not provide specific information to include in this legislative report.

to other programs in this section. Significant information gaps include costs and to what extent the collection includes packaging.

- **Spain: SIGRE Program.** This national program allows consumers to return unused pharmaceuticals to local pharmacies for recycling or safe disposal. It is managed by SIGRE, a nonprofit funded by members of the pharmaceutical industry based on volume of sales. The program stands out as having fairly high per capita collection and is a product stewardship model that uses a stewardship organization. Significant information gaps include costs and to what extent the collection metrics include packaging.
- **Sweden: Apoteket AB Program.** This national program allows consumers, along with other types of facilities such as care centers, dentists, hospitals, veterinarians, and farmers, to return leftover pharmaceuticals to the state-owned, nonprofit retail pharmaceutical chain. The program stands out for being government managed and financed, and for having higher reported costs and higher collection rates. Significant information gaps include how the collection rate is calculated given the broader scope of the program and to what extent collection metrics include packaging.

CANADA

Health Canada reports on pharmaceutical programs in 13 provinces and territories. It specifically mentions four of these programs as achieving relatively high collection rates in either total amounts collected or on a per capita basis. These are noted below, along with the program in Ontario that started in July 2010, and offers some of the latest thinking on program design:

- **Alberta ENVIRx Program.** This province-wide program allows consumers to return pharmaceuticals to a majority of local pharmacies for safe disposal. It is mainly funded by industry, but also by small grants from the provincial government. The program stands out for being voluntary. Significant information gaps include costs and to what extent collection metrics include packaging.
- **British Columbia PCPSA Program.** This province-wide program allows consumers to return pharmaceuticals to a majority of local pharmacies for safe disposal. The program is managed by a stewardship organization called the Post Consumer Pharmaceutical Stewardship Association (PCPSA) and is funded by industry. The program stands out for having more complete reporting and cost information, and relatively low collection rates and high costs for a product stewardship program. Significant information gaps include to what extent collection metrics includes packaging, which can affect per capita costs and collection rates.
- **Nova Scotia Medication Disposal Program.** This province-wide program allows consumers to return pharmaceuticals to local pharmacies for safe disposal. The program is administered by the Pharmacy Association of Nova Scotia (PANS) and funded by industry. Pharmacies have the option of participation and, according to PANS, all choose to participate. Because the program is voluntary and does not have reporting requirements, minimal information is publicly available. However, Health Canada reports that it has a relatively high per capita collection as compared to other Canadian programs.
- **Ontario Orange Drop Program.** This province-wide program covering 22 hazardous and special wastes, including household pharmaceuticals started in July 2010. New regulations defined the term “used consumer pharmaceuticals” to cover pharmaceuticals sold by retail establishments and returned by consumers. Only these pharmaceuticals can be returned to pharmacies. Pharmacies follow newly

created rules for used consumer pharmaceuticals that are less stringent than rules established for pharmaceuticals that are returned to suppliers in a reverse distribution process; the latter requiring complex tracking of ownership. Consumers push pharmaceutical waste into a one-way collection container at their local pharmacy. The waste is picked up on a regular schedule or upon request when the bin is full. The program has been administered by Stewardship Ontario and funded by industry; however, starting in fall 2010, the province will begin to provide funding to municipalities for management of this and several other programs. Ninety percent of pharmacies participate and accept unused/out-of-date pharmaceuticals from consumers. Additionally, the program holds hundreds of collection events for multiple products and uses household hazardous waste depots as collection sites. The program has established a baseline and targets initially call for collecting 47 percent of available pharmaceuticals, increasing to 74 percent in 5 years.¹²

- [Saskatchewan Waste Disposal Program](#). This province-wide program allows consumers to return pharmaceuticals to participating local pharmacies for safe disposal. The program is managed by the Pharmacists' Association of Saskatchewan and funded by community pharmacies. This program is voluntary and does not have reporting requirements so minimal information is publicly available, but Health Canada reports that it has a relatively high per capita collection as compared to other Canadian programs.

2. National Programs

In addition to California laws and policies (see Section I, 4. *Current status of regulations, statutes, and policy*), there are several national efforts to address safe management of unwanted home-generated pharmaceuticals. These are found in federal policies, laws, and regulations, along with nationally-based efforts by nonprofits, including those identified below. As noted, there are no nationwide home-generated pharmaceutical waste collection programs in the United States; waste collection is a state and local managed program.

FEDERAL GUIDELINES

- The **White House Office of National Drug Control Policy** issued in October 2009 new guidelines, *Proper Disposal of Prescription Drugs* (federal guidelines), to educate consumers about safe methods of pharmaceutical disposal.¹³ These guidelines first recommend participating in take-back programs, if available. When that option does not exist, it is recommended that drugs be removed from original containers and mixed with undesirable substances (like coffee grounds or cat litter), and then sealed in an impermeable container before throwing the unused drugs in the trash.

These federal guidelines address the concern of removing unwanted pharmaceuticals from households to minimize drug abuse. When the policy is followed, unwanted pharmaceuticals are placed in containers and are undistinguishable from other containers in household trash, making it more difficult for someone to find and abuse them. Furthermore, disposal in household trash is convenient and removes pharmaceuticals from homes at no additional cost to consumers. Several states actively promote the federal guidelines in their programs and provide information to consumers about how to hide and disguise unwanted pharmaceuticals in household trash, when local collection programs are not available (see Section II, 3. *State Programs* below). Additionally, the U.S. Food and Drug Administration developed [educational materials for consumers](#) on these guidelines.¹⁴

By recommending disposal in household trash, the federal guidelines alleviate the concerns of improper disposal of pharmaceutical waste into sewer systems that results in pharmaceuticals entering waterways and drinking water. On the other hand, a main drawback with the federal guidelines is that pharmaceuticals can then be deposited in landfills where they may eventually be able to leach into ground and surface waters. However, CalRecycle received numerous comments about this issue and reports to date (several of which are funded by industry) indicate this is a minor impact (see Appendix C: *Overview of Reports on Pharmaceuticals in Landfill Leachate*).

FEDERAL LEGISLATION AND REGULATIONS

While no national laws directly govern home-generated pharmaceutical waste, once home-generated pharmaceutical waste is collected at a consolidation point, it is subject to at least four national laws.

- The **U.S. Controlled Substances Act** regulates the manufacture and distribution of narcotics, stimulants, depressants, hallucinogens, anabolic steroids, and chemicals used in the illicit production of controlled substances, and defines who may possess controlled substances. Controlled substances must be collected by sworn law enforcement officers (pharmacies may only take back uncontrolled substances).

Program managers in California and in other states have viewed the federal Controlled Substances Act as a barrier to collection because it limits unsorted returns of controlled substances to law enforcement, which generally is less convenient than collection programs at local pharmacies. Consumers often times do not know and cannot easily determine if a drug is a controlled substance. Finally, in some regions of California, local jurisdictions report that law enforcement has placed higher priority on other responsibilities and has been unwilling to participate in collection activities. Additionally, residents are not as familiar with, and in some cases are reluctant to visit, law enforcement locations.

- In October 2010, President Obama signed into law the **Secure and Responsible Drug Disposal Act of 2010** (United States Senate, S. 3397, 111th Congress). This law gives the Attorney General authority to promulgate new regulations, within the framework of the Controlled Substances Act, which will allow patients to deliver unused pharmaceutical controlled substances to appropriate entities for disposal in a safe and effective manner consistent with effective controls against diversion. This law is intended to make it easier to collect and dispose of controlled substances while preventing illegal diversion of drugs. The process to develop new regulations could take a few years and, until that time, it is not completely known what the outcome will be. These new regulations are expected to impact collection programs in California since more program types could potentially begin collecting controlled substances.
- The **Resource Conservation and Recovery Act (RCRA)** governs the management of hazardous wastes at the federal and state levels, including some waste drugs. RCRA excludes from regulation pharmaceutical waste produced by individuals in their homes. States can choose to be more stringent, as California has (California Code of Regulations Title 22, Section 66261.101). However in this case, if a home-generated pharmaceutical is not a RCRA-regulated hazardous waste, it is not subject to California hazardous waste control laws. Thus, home-generated pharmaceutical waste is not regulated as hazardous waste in California unless it is comingled with other hazardous waste. This often occurs at household hazardous waste facilities where it is a general practice to comingle these wastes.

- **Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180)** determine how to classify and transport chemotherapeutic and some pharmaceutical wastes. However, household waste, which includes home-generated pharmaceutical waste, is excluded from these requirements and the HMR would apply only if home-generated pharmaceutical waste is comingled with hazardous waste.
- The **Health Insurance Portability and Accountability Act (HIPAA)** provides a federal floor of privacy protections for an individual's health information when that information is held by a covered entity or by a business associate of the covered entity. With respect to home-generated pharmaceuticals, HIPAA concerns are associated with patient information that may be contained on any packaging that is returned along with the waste.

NATIONWIDE EFFORTS

- The **American Medicine Chest Challenge** is a nationwide take-back event that occurred on Nov. 13, 2010.¹⁵
- The **Drug Take-Back Network** provides a clearinghouse of information on pharmaceutical take-back programs across the United States covering national, state and local programs. More information is available at: www.takebacknetwork.com
- The **National Prescription Drug Take-Back Campaign** was coordinated by the DEA to remove potentially dangerous controlled substances from medicine cabinets across the nation. State and local law enforcement agencies collected more than 242,000 lbs of drugs from more than 4,000 sites in all 50 states at this first-ever nationwide program held Sept. 25, 2010.¹⁶
- The **U.S. Postal Service (USPS) Prescription Mail Back Pilot Program** is intended to provide an estimated 780,000 veterans in Baltimore, Md., Washington, D.C., and West Virginia the opportunity to safely dispose of expired and unused prescriptions and help the environment. The program is being administered by the USPS and the U.S. Department of Veterans Affairs and allows veterans to mail outdated, unwanted medicine to federally-approved facilities where it is safely destroyed. Veterans receive specially designed, postage-paid envelopes and instructions with their prescription fulfillment. Expired and unused pharmaceuticals placed in the special packaging can be dropped in familiar blue USPS collection boxes or at post offices. The envelopes are delivered to facilities regulated and approved by the U.S. Environmental Protection Agency (EPA) and DEA. Pharmaceuticals from this and other similar mail-back initiatives are destroyed in accordance with EPA and DEA standards, including cataloguing and use of incineration, chemical or thermal processes.¹⁷
- The **Product Stewardship Institute (PSI)** works with stakeholders nationwide to develop product stewardship approaches for the end-of-life management for many difficult-to-manage unwanted/waste products, including pharmaceuticals. The main goals of the PSI multi-stakeholder dialogue are to increase awareness and to create a national, sustainable system for the end-of-life management of unwanted/waste pharmaceuticals.¹⁸

3. State Programs

At this point, several states have undertaken pilot programs to test methods for collecting home-generated pharmaceuticals. Washington and Maine's pilot programs stand out, for example, for being complete and

provide fairly detailed information about costs and collections rates. Overall, among all pilot programs researched, there is a need for:

- Sustainable funding;
- Safe and legal disposal for home-generated pharmaceuticals;
- Convenient collection through pharmacies, other collection sites, and mail-back programs; and
- Amendment to the Controlled Substances Act to allow for the collection of prescribed controlled substances at pharmacies.

In addition to pilot programs, some states promote the National Drug Control Policy (see “federal guidelines” in Section II, 2. *National Programs* above) and also allow home-generated pharmaceuticals to be incinerated at waste-to-energy facilities with other municipal solid waste.

Several state programs are listed below. These programs exclude controlled substances, unless noted:

- **Colorado:** The Colorado Department of Public Health and Environment and a consortium of concerned organizations have launched a pilot program, to run through 2011. This program seeks to provide a secure and environmentally responsible way for people to dispose of unwanted medicines, excluding controlled substances. Tamper-resistant collection boxes are available at 10 locations around the Denver metro area, including several stores, two county health department offices, and a health clinic. Funding is provided by federal, state and local government agencies (e.g., public health, water and environmental agencies), and pharmaceutical and nonprofit organizations.¹⁹
- **Florida:** The Florida Department of Environmental Protection promotes the National Drug Control Policy guidelines through educational materials. Brochures in English and Spanish inform Florida residents not to flush unused pharmaceuticals down the drain and explain how to dispose of unwanted pharmaceuticals in household trash. The state distributes information to consumers through pharmacies and through its website on medications management: www.dep.state.fl.us/waste/categories/medications/default.htm. This website includes research papers, presentations and disposal guidelines. All household-generated pharmaceutical waste, including waste from collection programs, and pharmaceuticals that are evidence or confiscated by law enforcement, are allowed to be burned in Waste-to-Energy (WTE) facilities whether or not they would otherwise be hazardous waste. WTE permit conditions allow for pharmaceuticals to be burned so long as they do not exceed 3 percent of total throughput.²⁰
- **Iowa:** The Iowa TakeAway program aims to provide the public with a safe, easy way to properly dispose of unwanted and expired medications, excluding controlled substances. TakeAway uses community pharmacies across the state as take-back sites. Some participating pharmacies also sell TakeAway envelopes, pre-addressed, pre-postage paid large envelopes that can be taken into the home, filled with unused and expired medicine, and mailed through the United States Postal Service to a disposal facility. Funding was provided through Iowa Department of Natural Resources grants to the Iowa Board of Pharmacy, which worked closely with the Iowa Pharmacy Association, to offer the TakeAway pilot program. The \$165,000 grant paid for collection in 357 pharmacies and as of May 2010, 2,550 lbs were collected and destroyed (this does not count partially filled bins).^{21, 22}
- **Maine:** The Safe Medicine Disposal for ME Program is a statewide pilot program for the disposal of unused household medications using a mail-back return envelope system.²³ The program was

established through state legislation and implemented in 2007 with a \$150,000 grant from the EPA's Aging Initiative. The program was authorized to handle both controlled and non-controlled medications. All drugs collected undergo high-heat incineration, according to the procedure already established for Maine's law enforcement drug seizures. Costs were \$18.79/mailed, including both actual and in-kind costs during the start up (phase I and II); long-term costs are anticipated to be \$7.50/mailed (phase III). The average weight of a mailed with drug waste is seven ounces. A report on the statewide mail-back model concludes that mail-back offers "an element of confidentiality and anonymity not found with in-person take back programs and is the least burdensome of all models in terms of consumer access and utilization." It further states that "Maine's citizen mail-back program has demonstrated that this approach is not only feasible, but effective." More recently, the Maine Department of Environmental Protection reported on research that found leachate in three lined landfills that contained a large variety of pharmaceuticals and personal care products.²⁴ (Also see Appendix C)

- **Massachusetts:** The Massachusetts Department of Environmental Protection has a comprehensive program to study and monitor pharmaceuticals in state waters. Department personnel are working with related agencies and stakeholders to reduce the amount of medications going to wastewater treatment plants, and to keep the public informed about the issues. Additionally, Massachusetts also promotes National Drug Control Policy guidelines, calling for participation in local collection programs, and if none are available then disposing of pharmaceuticals in household trash using the federal guidelines. More information is available at: www.mass.gov/dep/toxics/stypes/ppcpedc.htm.²⁵
- **New York:** The New York Drug Management and Disposal Act (2008) requires stores that sell pharmaceuticals, vitamins, supplements, and over-the-counter medications to display posters about how to properly dispose of drugs as part of the "Don't Flush Your Drugs" public awareness campaign. Instead of flushing medicines, households are encouraged to take advantage of community drug take-back programs that collect drugs at a central location for proper disposal. Collection event organizers must develop a collection plan, work with local law enforcement to secure the drugs at the collection event and obtain a variance, which allows the collected pharmaceuticals to be incinerated at waste-to-energy facilities within the state. Collection events to collect controlled substances must be approved by the New York State Department of Health, Bureau of Narcotic Enforcement. Households that are not able to take unwanted pharmaceuticals to collection events are advised to place their unused, unwanted, or expired drugs in the trash, taking care to destroy or disguise them to avoid misuse or misdirection with the suggestion of adding water, salt, ashes, or coffee grounds to unused medications before placing them in the trash. Detailed instructions and suggestions are available on the New York Department of Environmental Conservation website www.dontflushyourdrugs.net.²⁶
- **Texas:** To help ensure unused pharmaceuticals do not enter a wastewater system, the Texas Commission on Environmental Quality is conducting a study and submitting recommendations to the Texas Legislature on the methods currently used in the state to safely handle and dispose of pharmaceuticals, medical sharps, and other potentially dangerous waste. The recommendations also suggest alternative methods used for that purpose, including the methods used in other states; and the effects of the various methods on public health and the environment. The report is due in December 2010.²⁷
- **Washington:** To address the need for a safe way to dispose of unwanted medicines, excluding controlled substances, a coalition of government, nonprofit, and business partners began a 2006 Washington state pilot program called Pharmaceuticals from Households: A Return Mechanism (PH:ARM). The program took place at Group Health Cooperative, a regional healthcare organization

in Washington; Bartell Drug, a Western Washington retail pharmacy chain; and two boarding homes. Key findings of the PH:ARM pilot program are:

- Medicine return programs can provide environmentally sound disposal of medicines.²⁸
- Returning medicines to a pharmacy with proper oversight and strict protocols can be safe and secure for any type of medicine, including controlled substances.
- Medicine return programs are cost-effective to operate.
- The Controlled Substances Act should be changed to allow collection of legally prescribed controlled substances at pharmacies.
- A statewide program could collect a substantial amount of unwanted medicines.
- Pharmacy-based medicine return is convenient and effective.
- Community demand for safe disposal of medicines is high.
- Sustainable funding is needed for a statewide medicine return program.

Additionally, many local governments and groups of states host collection events. For example, in Maryland, seven counties collect pharmaceuticals and a regional program is under way with the EPA and four states that focus on the Potomac River watershed.²⁹

PROPOSED AND ENACTED STATE-LEVEL LEGISLATION

Several states (Florida, Maine, Maryland, Minnesota, Oregon, Rhode Island, and Washington) have proposed product stewardship legislation for pharmaceuticals, but as of September 2010, none have passed as such. Minnesota enacted House File 1217 that enables various parties including licensed HHW facilities and county collection programs to have possession of prescription drugs for the purpose of disposal.

PSI tracks pharmaceutical take-back legislation and is a source for more current information. See: www.productstewardship.us/ (select: products, pharmaceuticals).

III. Challenges and Barriers to Implementing a Model Collection Program in California

CalRecycle worked closely with numerous agencies to develop the Model Guidelines³⁰ that were formally adopted by the department in November 2008, with a subsequent revision in February 2009. Agencies participating included the California Department of Public Health (CDPH), the Department of Toxic Substances Control (DTSC), the State Water Resources Control Board (SWRCB), and the California State Board of Pharmacy (CBOP), and as well as other stakeholders. The Model Guidelines contain criteria and procedures for model pharmaceutical waste collection programs by type of program. Programs are not required to follow the Model Guidelines but they must be consistent with them to be considered a “model program” under SB 966.

This section discusses the following five challenges and barriers common among California home-generated pharmaceutical collection programs:

1. High Cost of Safe Collection;
2. Lack of Public Awareness and Participation;
3. Lack of Sustainable Funding;
4. Lack of Goals; and
5. Complexity of Current Requirements, Policies and Authority.

Through survey information presented and discussed in Section IV, CalRecycle identified these challenges and barriers for current programs. The surveys focused on implementation of the Model Guidelines (see Appendix D: *Criteria and Procedures for Model Home-Generated Pharmaceutical Waste Collection and Disposal Programs*) and for this reason, the explanations below reference the Model Guidelines.

1. High Cost of Safe Collection

Certain requirements in the Model Guidelines present unique challenges to some collection programs. Safety (security) issues are usually the primary reason why existing programs do not qualify as model programs. Meeting the requirements often can add more costs as specific participants are required (law enforcement personnel and registered haulers), more bins and pickups are needed (two-key bins and secured containers), and special handling considerations are implemented (separate handling, weighing, and record keeping). Treating home-generated pharmaceutical waste as medical or hazardous waste either through transportation or disposal (e.g., incineration vs. hazardous waste landfills) can also be costly. A few of these issues are illustrated in this section.

COLLECTION OF CONTROLLED SUBSTANCES

Controlled substances represent approximately 10 percent of all prescriptions written in the United States. In the state of Maine’s recent pilot mail-back program, controlled substances represented 17 percent of all

drugs returned. Given that many take-back programs cannot accept controlled substances, mail-back may offer convenience and privacy with these sensitive drugs.

Under federal statute (the U.S. Controlled Substances Act), controlled substances cannot be collected unless a sworn law enforcement officer is onsite to take custody of, document, and dispose of these medications to prevent illegal diversion and abuse. Based on information available to CalRecycle, the United States is the only country that has these requirements (see Section II, *1. International Guidelines and Programs*).

Making it easier for non-law enforcement programs to collect controlled substances, and making it easier to dispose of all home-generated pharmaceutical waste within California, would decrease costs and make program implementation easier and more attractive as may occur when regulations are promulgated as part of the recently passed S. 3397 (also see Section II, *2. National Programs, Federal Legislation and Regulations*).

HAULING CONSOLIDATED WASTE

If home-generated pharmaceutical waste is consolidated, CDPH considers it medical waste, which must be transported by a registered medical waste hauler. Transporting collected home-generated pharmaceutical waste using only haulers registered with CDPH may be more expensive than other options. At least nine pharmacies in the state used the larger cardboard “mail-back” boxes but this method does not use a registered waste hauler.

INCINERATION USED MORE THAN LANDFILLS

Disposal requirements and disposal options vary depending on how the materials are collected, consolidated, mixed with other materials, and on who does the collecting. The costs of these options are very different and impact the costs of collection programs.

BUSINESSES

Businesses tend to prefer the least expensive disposal option, which could be at in-state landfills. However, shipping home-generated pharmaceutical waste with existing larger volumes of medical or hazardous waste that are sent out of state for incineration may be more efficient than in-state landfill disposal. For instance, a relatively small amount of home-generated pharmaceutical waste could be sent in a small truck to an in-state hazardous waste landfill. However, that truck would be taken out of circulation from local hauling collection routes. In contrast, larger volumes of medical or hazardous waste are already sent out of state for incineration so combining all of these wastes may be less expensive overall.³¹ Shipping pharmaceutical waste to landfills in California may also be more expensive depending upon the infrastructure of the company collecting the waste. Some companies haul waste and operate incinerators out of state and may find that their overall internal costs are lower to ship to their incinerator than to use an in-state landfill.³²

LAW ENFORCEMENT

If controlled substances are collected, they must be incinerated (i.e., “destruction”) according to federal law.[‡] California law enforcement agencies that collect controlled and/or non-controlled substances generally use two in-state waste-to-energy incinerators, which are permitted to accept this waste, but not medical waste, hazardous waste, or liquids.³³ Commercial medical or hazardous waste haulers that cannot use these in-state waste-to-energy incinerators for their medical or hazardous waste, also collect non-controlled substances at some law enforcement sites and send it out of state for incineration because of the lower internal costs.

HHWs

Generally, HHW collection programs comingle home-generated pharmaceutical waste with other household hazardous wastes such as pesticides. The standard practice is for local governments to send out a Request for Proposals, select a commercial hauler with the winning bid, and the hauler usually chooses the disposal facility location. Because there are no known commercially-available medical waste or hazardous waste incinerators in California, the hazardous waste hauler generally ships it out of state for incineration.^{34,35}

As described above, businesses, law enforcement and HHW programs may choose incineration more often because it allows controlled substances to be handled correctly and because the overall cost/benefits may be greater for incineration over in-state hazardous waste landfill disposal. In the future, if larger collection volumes could be managed at in-state disposal facilities, cost efficiencies could improve.

TWO-KEY LOCKING COLLECTION BINS

To meet the Model Guidelines, bins located at pharmacies must have a two-key security system so that no individual may access the drug waste alone: the pharmacy’s designated responsible person would have one key and the licensed hauler would have the other key. In addition, to save on waste hauling expenses, employees at many pharmacies with publicly accessible bins will empty the bin and store the bin contents behind the counter to avoid extra waste hauler trips. The two-key security system complicates pharmacies’ attempts to minimize waste hauler trips and consolidate waste when bins are full. For example, Marin County, which began collection in 2004, would exceed its \$14,000 annual budget if the county paid for a two-key collection bin for each of its 24 participating pharmacies. Also, based on written stakeholder comments after the July 20, 2010 workshop, if three specific pharmacy programs (representing 17 pharmacies) switched to the two-key system it would increase their annual costs by 141 percent (from \$30,700 to an estimated \$73,900, with an additional one-time cost of \$15,360 for bin purchases).³⁶

USE OF SECURE CONTAINERS AT HHW SITES

The majority of HHW facilities comingle drug waste with other HHW—often in open 55-gallon drums to allow room for other waste to be deposited easily. Unfortunately, this also allows much easier access to deposited pharmaceuticals. To meet the Model Guidelines, an additional bin may be needed (at a cost of approximately \$600 each) so materials are not comingled and remain secure. However, the relatively small amounts of pharmaceutical waste compared to other waste collected at HHW sites makes it somewhat

[‡] Controlled Substances Act, Section 881 (f)(2) and Code of Federal Regulations, Section 1307.21 (b)(3)

impractical for pharmaceuticals to be managed separately from other HHW; it could lead to prolonged storage times and much higher disposal costs (costs rise exponentially for smaller containers).

RECORD KEEPING AND DATA COLLECTION

Weighing, logging and tracking drug waste before and after transport is meant to prevent illegal diversion, and can also be useful in performance measures. Most survey respondents for HHW facilities reported they comingled pharmaceutical waste with other HHW, which may make it more difficult to weigh, log and track pharmaceuticals separately. As discussed above, if HHW sites must treat other waste and pharmaceuticals differently, their costs will be higher.

2. Lack of Public Awareness and Participation

A common challenge with any type of collection program is achieving high public awareness and participation rates. Local governments facing significant budget shortfalls fund most collection programs. Given that program costs increase with more collection, local governments are in one sense penalized as participation increases.

There is not enough data from programs outside of California to draw any conclusions about types of programs associated with high public participation, but anecdotally, public outreach and convenience play an important role.

3. Lack of Sustainable Funding

Local governments currently fund approximately 83 percent of all California collection programs. Of that percentage, most funding comes from counties, local waste and water agencies, and to a lesser extent, cities. Pharmacies provide funding for 15 percent of collection programs. The remainder comes from various other sources, such as nonprofit organizations and waste companies. Although SB 966 encourages a cooperative relationship with all stakeholders, CalRecycle is not aware of any funding from pharmaceutical manufacturers for collection programs in California. However, there is public support for pharmaceutical companies assuming this responsibility. According to a recent survey of consumers in Washington and Oregon, 64 percent of those who responded agreed (strongly or somewhat) that pharmaceutical companies should be responsible for creating a take-back program for safe disposal of unused medicines.

This contrasts significantly with other countries (See Section II. Overview of Programs Outside of California), where private sector manufacturers and retailers play a significant role in funding and managing pharmaceutical collection programs, many through product stewardship programs. Product stewardship programs use a private-sector approach to managing discards.³⁷ Producers are generally able to implement programs either individually or by joining together with other producers through a product stewardship organization that collects, properly manages, and interacts with the state oversight agency on its behalf.

4. Lack of Goals

There are two basic reasons for implementing pharmaceutical collection programs that address improper disposal. The first is to reduce the amount of pharmaceuticals that enter the environment, particularly in surface and groundwater. The second reason is to reduce illegal diversion of pharmaceuticals and prevent drug abuse. Goals set for the collection of unwanted household pharmaceuticals must address both reasons.

SB 966 does not provide any performance goals to measure success. Performance goals similar to CalRecycle's goal of 50 percent waste diversion in California by the year 2000 could drive the creation of programs and help set realistic standards for pharmaceutical waste collection throughout the state. Goals accompanied with incentives (e.g., limiting long-term corporate liability³⁸) can be particularly effective in driving program activity. To be effective, measures must take into account information about the amounts of pharmaceuticals sold/prescribed in California, the amounts unused, and the amounts that are eventually collected.

Additionally, a subset of measures could help track program effectiveness and guide program improvements. For example, some studies indicate that pharmaceuticals enter surface and groundwater largely due to human excretion (see Appendix C: *Overview of Reports on Pharmaceuticals in Landfill Leachate*). This suggests that collection programs may not make a large reduction on pharmaceuticals water emissions, even if programs collect all unwanted drugs. However, the studies are industry-sponsored and few in number, making it difficult to draw firm conclusions. Tracking pharmaceutical impacts on water quality could provide a deeper understanding of pollution sources and aid in finding effective solutions.

Even if goals are established, an entity must have the authority to gather necessary data from participants in order to measure progress toward meeting these goals. Otherwise, based on CalRecycle's experience with other collection streams and based on staff knowledge of pharmaceutical collection programs outside of California, there will not be data available to determine whether goals are met or if the program is successful.

Regardless, however, there is agreement that substance abuse is a growing concern among families and communities; and providing convenient collection, supported with public education, could help address this issue. In addition to establishing collection goals, programs could also establish convenience goals and track educational efforts to better ensure adequate public participation.

5. Complexity of Requirements, Policies and Authority

The Model Guidelines state, "Any participating entity must determine what permits or approvals are needed for home-generated pharmaceutical waste collection." However, the current patchwork of laws, regulations, and policies can be a challenge for any collection program. For example, Waste Management, Inc., reports that California's regulation of pharmaceutical waste is "extremely complex and these wastes may be regulated as a hazardous waste, a medical waste, or a solid waste under California law."³⁹ Entities may be discouraged from starting collection programs due to concerns and uncertainty about the applicable definitions, requirements and legal options for collecting, handling and disposing of home-generated pharmaceutical waste. Through statute, regulation, or policy, each of the following federal and state departments affects the collection and disposal of home-generated pharmaceutical waste to some degree (also see Section I, 4. *Current status of regulations, statutes, and policy*).

- **U.S. DRUG ENFORCEMENT ADMINISTRATION (DEA)**

There are no DEA regulations specific to home-generated drug collection, but under the U.S. Controlled Substances Act the DEA governs controlled substances (Title 21, Chapter 13, Drug Abuse Prevention and Control). These regulations oversee the manufacture and distribution of narcotics, stimulants, depressants, hallucinogens, anabolic steroids, and chemicals used in the illicit production of controlled substances and define who may possess controlled substances, which impacts disposal of a controlled substance. The Secure and Responsible Drug Disposal Act

of 2010 (S 3397) (See Section II. Overview of Programs Outside of California), amends the Controlled Substances Act to allow for the safe and effective collection and disposal of controlled substances. The specific changes will be forthcoming through a rulemaking process to start in late 2010, at the earliest.

- **CALIFORNIA BOARD OF PHARMACY**

Pharmacies lack statutory provisions for pharmaceutical collection, unlike the recently granted provisions for sharps collection. California law currently does not authorize pharmacies to accept the return of home-generated pharmaceutical waste. SB 966 states programs consistent with the Model Guidelines are "...in compliance with state law and regulation..." but SB 966 did not amend the Business and Professions Code to specifically authorize pharmacies to accept home-generated pharmaceuticals, which creates some confusion about how to interpret the legalities of pharmacy participation. Regardless, the California Board of Pharmacy's February 2010 newsletter stated, "The Board expects all pharmacies to use the [CalRecycle] Guidelines for any 'Take Back' program they offer the public."⁴⁰

Likewise, California law did not authorize pharmacies to accept the return of sharps from the public until Senate Bill 821 (Committee on Business, Professions and Economic Development, Chapter 307, Statutes of 2009) added appropriate language to the Business and Professions Code in October 2009. Until that time, the California Board of Pharmacy had a stated policy that it did not anticipate intervening in sharps collection programs unless necessitated by a complaint or public safety issue. A similar provision in California law would clarify the requirements for home-generated pharmaceutical waste.

- **DEPARTMENT OF TOXIC SUBSTANCES CONTROL (DTSC)**

DTSC regulates hazardous waste including approximately 5 percent of all pharmaceutical waste⁴¹ (e.g., nitroglycerin, warfarin, and some chemotherapy agents dispensed from hospitals), but does not regulate home-generated pharmaceutical waste. DTSC's website states, "Pharmaceutical waste produced by a household is exempt from classification as hazardous waste or medical waste. This means that a household may legally dispose of their waste pharmaceuticals and personal care products in the solid waste stream or into the sanitary sewer ('down the drain'). While these practices are legal, they may not be the environmentally preferred ways for a household to dispose of unwanted pharmaceuticals."⁴²

- **CALIFORNIA DEPARTMENT OF PUBLIC HEALTH (CDPH)**

The Medical Waste Management Program of the CDPH does not have statutory authority to regulate home-generated pharmaceutical waste. Instead, CDPH applies a best waste management policy consistent with current, existing waste collection models for home-generated pharmaceutical waste. This current policy monitors home-generated pharmaceutical waste at registered consolidation points to ensure proper containment, storage, and treatment. CDPH's policy is similar to its current regulation of home-generated sharps waste, which it defines as medical waste, when the sharps are collected at a consolidation point.

As noted, there is an absence in current statute of a specific definition of home-generated pharmaceutical waste and which agency has authority regardless of how it is collected, consolidated, managed and disposed. Instead, various federal and state departments (DEA, Board of Pharmacy, DTSC, CDPH) exercise statutory authority, regulatory authority or have current policies over home-generated pharmaceutical collection, management, and disposal with different levels of consistency and clarity. In turn, the separate statutes, regulations and policies can make it challenging for local jurisdictions to develop and maintain effective collection and disposal programs that they know conform to legal requirements. Clear statutory definition of which department or agency has sole authority over defining home-generated pharmaceutical waste and determining issues related to collection, consolidation, management, and disposal is essential to providing for a successful program that safely manages collection and disposal of home-generated pharmaceutical waste.

IV. Program Surveys and Results

1. Nearly All Programs Returned Surveys

During April and May 2010, CalRecycle sent surveys to 67 program managers representing 297 known home-generated pharmaceutical collection programs.[§] This report includes results based on the surveys returned to the department by June 10, 2010.

Many program managers represented more than one program and often more than one type of program. A one-page survey covered each of the three major program types (continuous collection programs, events, or mail-back programs, which are described below). As a result, a program manager may have filled out numerous surveys (one for each program) using the appropriate survey forms.

The survey forms listed at the [SB966 Pharmaceutical Drug Waste Disposal Program Workshop](http://tinyurl.com/July2010PharmaWrkshop) web page (<http://tinyurl.com/July2010PharmaWrkshop>) varied by program type and included up to 25 questions that requested information on operations, funding, costs, collection amounts and security practices related to the standards in the Model Guidelines, over an eight-month period. Not all of the surveys were complete and some appeared to contain contradictory, unsupported, or unexplained responses. This is expected when dealing with complex topics and self-directed survey instruments.

Three main types of programs collect home-generated pharmaceuticals in California: continuous collection programs, events, or mail-back programs.

- **Continuous collection programs** are defined as drop-off locations that have scheduled collection hours at least weekly throughout the year.^{**}
- **Collection events** are defined as programs that provide:
 - Periodic drop-off opportunities at different locations, or
 - Infrequent drop-off opportunities at a single location, in comparison to continuous collection programs (e.g., an average of one or two days each month or less at the same location).
- **Mail-back collection programs** are defined as programs that transport drug waste through the USPS to an appropriate disposal location.^{††}

[§] CalRecycle became aware of these programs through workshops, discussions and other communications. Additional programs may exist.

^{**} CalRecycle acknowledges that there is a spectrum of collection frequencies and approaches. The line between continuous collection programs and collection events is not black and white. For the purposes of this analysis, CalRecycle chose weekly collection as the threshold to distinguish between the two.

^{††} Some pharmacies use tamper-resistant cardboard “mail-back” boxes (which hold 10 or 20 gallons). Pharmacies keep these containers on site until they are full. Individual consumers do not use these boxes, so this practice is included as part of the continuous collection programs operated at pharmacies.

Overall, CalRecycle identified 297 collection programs and program managers returned surveys for 256 programs (86 percent of total). The return rate varied by collection program as shown in Figure 2. The percentage of responses in each program type adequately represents current collection efforts in California.

Figure 2. Number of Programs and Number of Survey Responses by Program Type

	Number of Known Individual Programs	Total Number of Individual Programs Represented in Survey	Percentage of Programs with Survey Responses (%)
Continuous Collection			
- Pharmacies	112	102	91%
- Law Enforcement	65	63	97%
- Household Hazardous Waste Facilities	26	18	69%
- All Other	38	24	63%
Collection Events	53	46 ^{††}	87%
Mail-back	3	3	100%
Total	297	256	86%

Based on the survey responses, the primary locations for continuous collection programs are pharmacies (102), law enforcement sites (63), and HHW collection sites (18). Ten other location types^{§§} contribute another 24 continuous collection sites, but the low numbers and differences between them make it difficult to draw conclusions regarding these locations.

The remainder of this report focuses on the top three continuous collection location types (pharmacies, law enforcement, and HHW), as well as collection events and mail-back programs.

The responding collection events range from regular mobile collection events to limited hours at permanent household hazardous waste sites (e.g., first Saturday of each month) to highly coordinated events at multiple sites in a one-week period. Typical collection events are located in parking lots, vacant lots, pharmacies, senior centers, police substations, and HHW facilities.

^{††} Program managers returned surveys for 50 of the known collection events. However, four surveys contained information from prior to 2009. CalRecycle became aware of two other programs after this analysis was completed. Finally, the “No Drugs Down the Drain” campaign consisted of more than 200 local one-day and ongoing pharmaceutical collection options during the week of Oct. 4-11, 2008. This campaign was not included because it predated the survey period. As a result, this paper reflects 46 survey respondents.

^{§§} Other locations include: clinics (6), hospitals (4), city halls (3), senior centers (3), dentists (2), door-to-door pickup (2), water districts (1), wastewater treatment plants (1), offices (1), and fire stations (1).

The three mail-back programs all began in the Bay Area in 2009: the City of San Francisco, Teleosis (a nonprofit organization in the Bay Area), and Santa Cruz County. While only a few mail-back programs currently operate in California, other states utilize mail-back collection programs (as discussed in Section II. Overview of Programs Outside of California).

The number of surveys used in different analyses within this report may vary because not all surveys included all the necessary information to complete the calculations or determinations for each question or topic.

The analyses in the remainder of this report are based only on the survey responses, which do not include all programs in the “known universe,” because the survey responses are considered “confirmed” programs and have data associated with them.

2. Approximately One-Third of Programs Meet the Voluntary Model Guidelines And So Are “Model” Programs

The Model Guidelines emphasize the secure management of home-generated pharmaceutical wastes. To be a model program, a program must meet each of the criteria in the guidelines. The Model Guidelines are not mandatory or regulatory, so program managers can choose whether or not to follow them. While the Model Guidelines were designed to improve the consistency and quality of collection programs in California, programs that do not meet these voluntary Model Guidelines can still produce good results. However, for the purposes of this report, a program that does not adequately meet all the criteria in the Model Guidelines is not considered a “model program.”

Based on responses on the 256 programs surveyed, CalRecycle determined that 89 (35 percent) met all the standards in the voluntary Model Guidelines and were therefore model programs while 167 did not meet at least one criterion. Some criteria in the Model Guidelines, certain survey questions, and several survey responses contained ambiguity, so CalRecycle’s model program determinations contain some subjective considerations. As shown in Figures 3 and 4, there are more model programs and higher percentages of model programs in some collection program types than other program types.

Figure 3. Numbers of Model and Non-Model Programs by Type

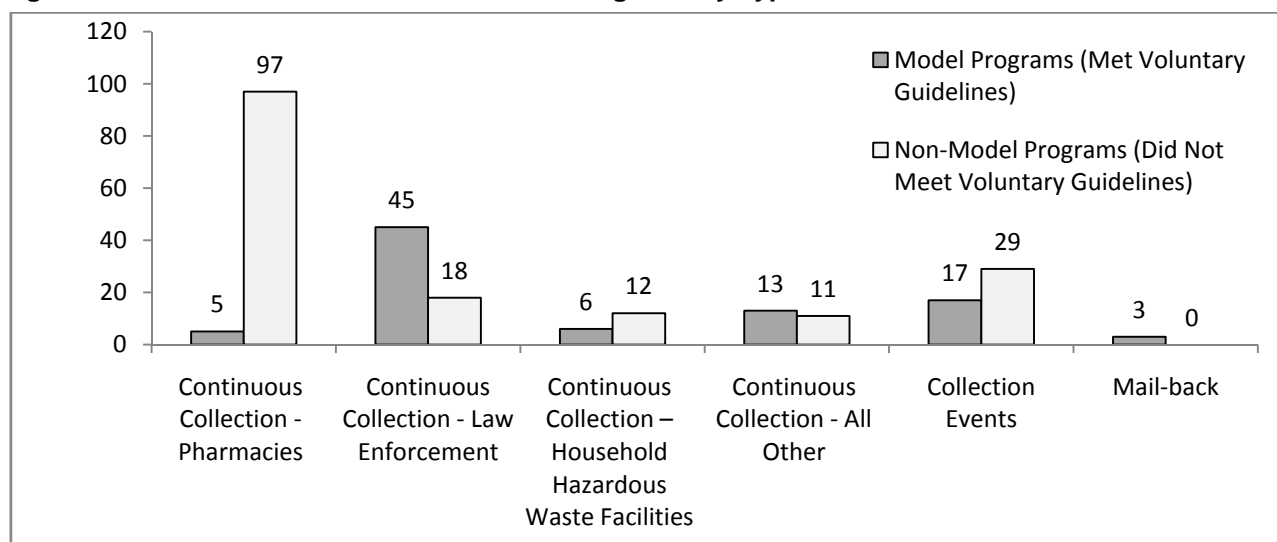


Figure 4. Numbers and Percentages of Model Programs

	Number of Model Programs (Met Voluntary Model Guidelines)	Number of Non-Model Programs (Did Not Meet Voluntary Model Guidelines)	Percentage of Model Programs Within Program Type
Continuous Collection			
- Pharmacies	5	97	5%
- Law Enforcement	45	18	71%
- Household Hazardous Waste Facilities	6	12	33%
- All Other	13	11	54%
Collection Events	17	29	37%
Mail-back	3	0	100%
Total	89	167	35%

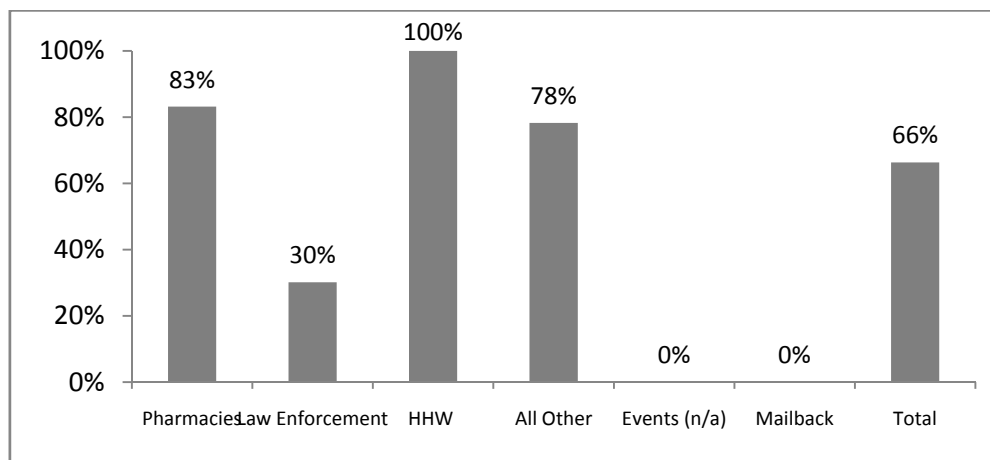
Of the 207 continuous collection programs, 69 adequately met the voluntary Model Guidelines and are model programs. Specifically, five pharmacy collection programs are models (5 percent), 45 law enforcement collection programs are models (71 percent), and 6 HHW collection programs are models (33 percent). Of the 46 collection events, 17 adequately met the voluntary Model Guidelines and are model programs (37 percent). Of the three mail-back collection programs, three adequately met the voluntary Model Guidelines and are model programs (100 percent). In general, mail-back and law enforcement programs most frequently met the Model Guidelines while pharmacies least frequently met them, but these conclusions need to be placed in context as discussed further below.

Some programs that existed prior to the adoption of the voluntary Model Guidelines have features that conflict with the guidelines. Figure 5 shows that most programs (136 out of 205 with data) were already operating at the time the voluntary Model Guidelines were approved in November 2008. Program managers had already invested significant time and/or resources to develop these existing programs, and changing them to meet the voluntary Model Guidelines prior to the survey period (approximately 18 months later) proved to be challenging for some. Changes that required additional infrastructure, resources or major changes to business procedures likely contributed to many programs not qualifying as model programs. As shown in Figures 5 and 6, nearly all of the pharmacy programs (83 percent) and all of the HHW (100 percent) were in place before the Model Guidelines were approved, which may help explain the lower rates of model programs in those two program types.

Figure 5. Number and Percentage of Programs Started Before Voluntary Model Guidelines Approved

	Programs that Predate Model Guidelines	Programs with known start dates	Percentage of Programs that Predate Model Guidelines***
Continuous Collection			
- Pharmacies	84	101	83%
- Law Enforcement	19	63	30%
- HHW	15	15	100%
- All Other	18	23	78%
Events	n/a	n/a	n/a
Mailback	0	3	0%
Total	136	205	66%

Figure 6. Percentage of Programs Started Before Voluntary Model Guidelines Approved



*** The percent of start dates reported out of the total survey responses were: pharmacies (99 percent), law enforcement (100 percent), HHW (88 percent), all other (96 percent), and mailback (100 percent) or 98 percent for all program types.

3. Different Programs Excel in Different Evaluation Areas: Safety, Accessibility, Cost-Effectiveness and Efficacy

This section evaluates five program types (Pharmacies, Law Enforcement, HHW, Collection Events, and Mail-Back) using the four factors specified in SB 966: safety, accessibility, cost-effectiveness, and efficacy. While SB 966 only calls for an evaluation of “model programs,” for completeness this paper analyzes all programs that responded to the surveys.

This section first presents the following two introductory subsections:

- **Definitions and Limitations.** CalRecycle presents definitions of the four evaluation factors for the purposes of this report, along with the major limitations associated with the analysis of each factor.
- **Program Evaluation Criteria Groupings.** CalRecycle groups the breaking points for each evaluation criterion into high, medium, and low categories.

CalRecycle then summarizes the results of the analysis and highlights the strengths and weaknesses of each of the following program types:

- **Pharmacy Program Evaluation**
- **Law Enforcement Program Evaluation**
- **HHW Program Evaluation**
- **Collection Event Program Evaluation**
- **Mail-Back Program Evaluation**

DEFINITIONS AND LIMITATIONS

Based on comments from numerous stakeholders, it is apparent that each of the following evaluation factors could be defined differently with different metrics. CalRecycle acknowledges this and, for the purposes of this report, uses the definitions provided below.

CalRecycle also acknowledges that there are analytical limitations associated with each evaluation factor. While the response rate was high, the non-respondents may have been able to provide critical data different from those program managers that responded. As with any survey, different program managers may have interpreted the questions differently. Additionally, ambiguity in some of the survey questions may have caused confusion or resulted in incorrect responses. Incomplete surveys caused voids in the analysis, regardless of what the answer might have been had the response been provided. None of these analytical limitations renders the analysis fatally flawed, but did result in a more subjective and qualitative analysis.

CalRecycle also cautions readers about trying to compare the different program types. First, the data varied significantly within each program type as well as between program types; when this type of variability exists, one must use caution when comparing averages. Second, the program types vary

tremendously in whom they serve and how they provide their services. By way of example, grocery stores, fast food chains and high-end restaurants all provide food but do so very differently and each type excels in different situations. Similarly, the fundamental differences in service delivery models in different pharmaceutical collection program types make comparisons fruitless.

SAFETY (SECURITY)

Safety pertains to the security of pharmaceutical waste collection to prevent illegal diversion. The voluntary Model Guidelines contain many criteria designed to prevent or deter the public and/or program employees from taking pharmaceuticals out of the collection system for abuse or sale. CalRecycle attempted to capture these criteria in the survey questions. “Safer” collection programs meet more of the criteria and the “safest” qualify as model programs. One unmet criterion disqualifies a program from being considered a model. Also note that it may be possible to develop alternatives to the existing safety criteria in the Model Guidelines if collection system improvements can be identified in the future (e.g., more advanced practices become feasible such as shredding drug waste within each collection bin, automatically counting/tracking each pill, or tracking each pill bottle by automatically scanning barcodes or using RFID [Radio-frequency identification] tags).

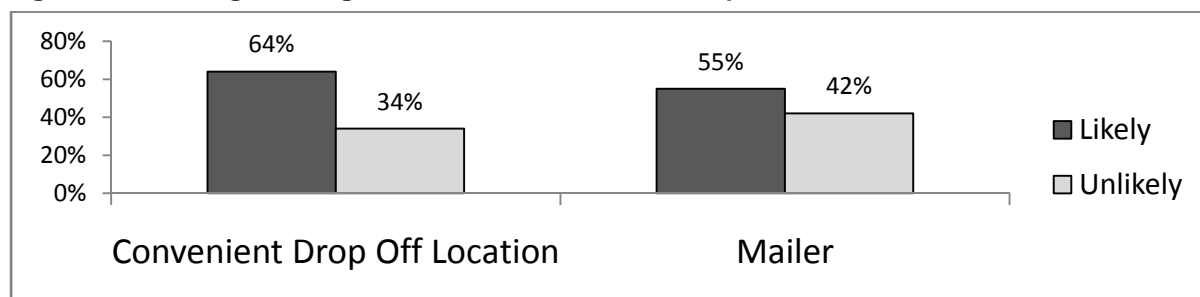
STATEWIDE ACCESSIBILITY (ACCESSIBILITY)

Public accessibility pertains to the ability of the public to utilize a collection program. Two factors that correlate to accessibility are the overall number of collection sites and their access hours. A tally of the returned surveys provides the number of sites for each program type, while the survey included questions regarding hours of operation per week.

It is important to realize that an increase in the number of collection sites in the state may not correlate to a more even geographic distribution throughout the state. Some people may not consider all types of sites equally accessible (e.g., anecdotal reports suggest some people are afraid of going to law enforcement sites), so the raw number may be misleading. Additionally, events may not be the most numerous programs, but in rural areas targeted local collection events could provide the easiest access compared to longer travel distances to continuous collection programs.

Accessibility is a very subjective measure. If tailored correctly to a target population, any or all of the program types could result in reasonable access for the public. Because accessibility is dependent on consumer behavior, consumer preferences will drive the actual use of collection programs. Based on a recent study of nearly 800 consumers in Washington and Oregon, 64 percent of those surveyed would be somewhat or very likely to take their home-generated pharmaceutical waste to a “convenient” drop-off location, while 55 percent of those surveyed would be somewhat or very likely to use a mail-back program for their home-generated pharmaceutical waste (see Figure 7 below).⁴³

Figure 7. Washington/Oregon Residents’ Medication Disposal Preferences



Hours of operation varied significantly within program type as well as between program types; readers should use caution when using or comparing averages when this type of variability exists. For example, among continuous collection programs, hours of operation may be a meaningful comparison. However, comparing these programs to mail-back programs is difficult, e.g., should the measure of accessibility for mail-back be picking up the envelope (limited hours) or putting it in the mail (unlimited hours)? In addition, the total number of hours may be less important than the “effective hours” in which people are likely to use a program, e.g., 24-hour access may not result in three times the effective access or triple the collection amounts compared to access during the “right” eight hours per day. Finally, because of their infrequent nature, collection events are not comparable regarding hours of operation but if tailored correctly to the population served could nonetheless be accessible.

COST-EFFECTIVENESS

Cost-effectiveness pertains to the amount of pharmaceuticals collected in comparison to the cost of the program used to collect them. CalRecycle’s survey included questions about quantities collected and costs incurred. For this analysis, this metric is the average cost per pound for each program type.

Responses that did not include both costs and pounds of pharmaceutical waste collected were not included in the cost-effectiveness analysis. Errors or misreporting in overall cost or amount collected will impact the reliability of the cost-per-pound calculation.

Program costs may include: 1) advertising costs; 2) a medical or hazardous waste hauler’s collection, transportation, disposal, and processing fees (hauler fees); and 3) administrative/staff time. Survey respondents could choose to provide costs for any or all of these categories. This analysis uses the cost data that program managers provided. For instance, many programs did not provide advertising costs because their program was mature enough that advertising was not needed, or funds were so limited that it was not an option. In addition, in many cases, staff time was not tracked and was not provided. Out of all survey responses, 51 percent of the programs and sites representing a cross section of all program types did not have associated staff costs. Because all costs were not included, the results presented here may be a low estimate. The cost data varied significantly within program type as well as between program types; when this type of variability exists, readers need to use caution when comparing averages.

CalRecycle did not adjust the reported amount of pharmaceutical waste collected to compensate for packaging discarded with the pharmaceuticals. While some programs encourage participants to remove packaging more than other programs, CalRecycle could not quantify the effect of this encouragement due to lack of accurate data. As a result, the cost effectiveness and efficacy relate to the combined weight of pharmaceuticals and associated packaging.

Most HHW programs do not track pharmaceutical weights separately from other household wastes they collect; most reported estimated weights. CalRecycle excluded one HHW program from the analysis because it reported a combined weight of household wastes and pharmaceuticals.

EFFICACY (COLLECTION RATE)

Efficacy is measured in three ways:

- The total amount of pharmaceutical waste collected by a program, divided by the number of operating days (pounds per operating day);
- The total amount collected by program type in California (total pounds per program type); and
- The average amount collected by each program type (average pounds per program).

A common criterion is pounds collected per capita; however, this metric does not work for this analysis because the population served by a collection program (e.g., one pharmacy) is unknown. As discussed above, both cost-effectiveness and collection rate rely on weight data for collected pharmaceuticals. CalRecycle did not adjust the reported amount of pharmaceutical waste collected to compensate for packaging discarded with pharmaceuticals. As a result, efficacy relates to the combined weight of pharmaceuticals and associated packaging.

For continuous collection programs, amount collected per day of operation equates to the amount collected at an individual site divided by the entire eight-month reporting period. For mail-back programs, the amount collected per day of operation equates to the amount collected from all mailers per program divided by the entire eight-month reporting period. For a one-day collection event, the amount collected is divided by one day to yield the pounds collected per day of operation. As a result, comparisons between continuous collection program types may be feasible. However, comparing these programs to collection events can be problematic because the boundaries of the program are less clear (e.g., a continuous collection program, a single envelope, a single event, all continuous collection programs, all envelopes, or the entire series of events).

PROGRAM EVALUATION CRITERIA GROUPINGS

Each program type can be effective in different situations and with different target populations. CalRecycle evaluated each program type based on the four criteria (safety, accessibility, cost effectiveness and efficacy) to determine current practices and results. This report represents a snapshot of pharmaceutical collection programs -- that is, as they were in late 2009 and early 2010. As programs continue to develop, they will evolve and may expand to fill new niches. Given the dynamic nature of this policy area, changes in statutes, regulations, and/or policy may dramatically change the way in which these services are delivered.

This section contains a factor-by-factor review of the information gathered during the survey, followed by a qualitative summary of each program type. As part of the qualitative summary, CalRecycle prepared a chart for each program type that visually illustrates the overall/average performance within each evaluation area (see Figure 8 for a blank sample). As noted above, it is difficult at best to compare results **across** programs, and CalRecycle has not done so in this analysis.

Figure 8. Relative Strengths of _____ Collection Programs

	Safety			Access			Cost	Efficacy		
	Number Models	Criteria Match	% Models	Current Sites	Hours/ Day	Possible Sites	Dollars/ Pound	Pounds/ Day	Current Pounds	Pounds/ Program
Strongest										
Medium										
Weakest										

CalRecycle has highlighted the appropriate box for each criterion examined in each program type to show relative strengths and weaknesses. When possible, CalRecycle used natural break points in the data for separating the program types into the “strongest,” “medium” and “weakest” categories; however, the groupings are by nature somewhat subjective; selecting different break points would show different summary results. Figure 9 below shows the break points used to evaluate each program type. Those break points are described further below.

Figure 9. Evaluation Criteria Break Points

	Safety			Access			Cost	Efficacy		
	Number Models	Criteria Match	% Models	Current Sites	Hours/Day	Possible Sites	Dollars/Pound	Pounds/Day	Current Pounds	Pounds/Program
Strongest	>30	0-2	>70%	>70	>10	>1,000	<\$3	>10	>10,000	>1,500
Medium	10-30	3-5	30%-70%	30-70	5-10	500-1,000	\$3-\$7	5-10	1,000-10,000	150-1,500
Weakest	<10	>5	<30%	<30	<5	<500	>\$7	<5	<1,000	<150

- Safety:
 - “Number Models” = total number of existing programs in California that are model programs (meet voluntary Model Guidelines).
 - Strongest: more than 30 programs
 - Medium: 10 to 30 programs
 - Weakest: fewer than 10 programs
 - “Criteria Match” = how well existing programs were able to meet the individual criteria in the voluntary Model Guidelines.
 - Strongest: 0 to 2 guideline criteria not met by program
 - Medium: 3 to 5 guideline criteria not met by program
 - Weakest: more than 5 guideline criteria not met by program
 - “% Models” = percentage of existing programs in California that are model programs (meet voluntary Model Guidelines).
 - Strongest: more than 70 percent of programs
 - Medium: 30 percent to 70 percent of programs
 - Weakest: fewer than 30 percent of programs
- Accessibility:
 - “Current sites” = total number of existing programs in California.
 - Strongest: more than 70 programs
 - Medium: 30 to 70 programs
 - Weakest: fewer than 30 programs
 - “Hours/Day” = the average number of hours programs are available per day.
 - Strongest: more than 10 hours per day
 - Medium: 5 to 10 hours per day
 - Weakest: fewer than 5 hours per day
 - “Possible Sites” = total number of potential sites in California.
 - Strongest: more than 1,000 potential sites
 - Medium: 500 to 1,000 potential sites

- Weakest: fewer than 500 potential sites
- Cost Effectiveness:
 - “Dollars/Pound” = the average dollars spent per pound of pharmaceuticals collected.
 - Strongest: less than \$3.00 per pound
 - Medium: \$3.00 to \$7.00 per pound
 - Weakest: more than \$7.00 per pound
- Efficacy:
 - “Pounds/Day” = the average number of pounds collected per day of operation.
 - Strongest: more than 10 pounds per day
 - Medium: 5 to 10 pounds per day
 - Weakest: less than 5 pounds per day
 - “Current pounds” = total amount collected by all existing programs in California.
 - Strongest: more than 10,000 pounds
 - Medium: 1,000 to 10,000 pounds
 - Weakest: less than 1,000 pounds
 - “Pounds/Program” = the average pounds collected by each program type.
 - Strongest: more than 1,500 pounds
 - Medium: 150 to 1,500 pounds
 - Weakest: less than 150 pounds

PHARMACY PROGRAM EVALUATION

SAFETY (SECURITY)

Program Safety (Security)

While 60 percent of the 102 responding pharmacy programs indicated that they were consistent with the Model Guidelines, CalRecycle determined that only 5 percent (5 programs) actually qualified as model programs. Pharmacy programs had issues with nine safety-related criteria; however, several of the criteria overlap and may artificially inflate this count. Three issues related to collection bin access and handling caused most disqualifications: two-key^{†††} bins (93 percent), locking full bins (84 percent), and public access to bins (65 percent)^{†††}.

As discussed above, most pharmacy programs predated the voluntary Model Guidelines so they may have more trouble converting over to the new criteria. Additionally, some pharmacies may not have been aware of the voluntary Model Guidelines or all the specific provisions until the Board of Pharmacy officially notified them in a newsletter just before the survey period (approximately March 2010).

^{†††} California’s Model Guidelines require that, “Bins located at pharmacies shall have a two-key security system--one in the possession of the collection site’s designated responsible person and the other in the possession of the licensed hauler who will pick up the contents for appropriate destruction.”

^{†††} The guideline requirements were designed to prevent pharmacy employees from individually accessing collected pharmaceutical waste and “public access to bins” indicates the pharmacy employees must handle collected pharmaceutical waste if the public does not have access to the collection bins.

Illegal Diversion Incidences

Any program's safety or security standards should be considered in the context of existing diversion incidences. Out of 256 collection sites or programs (including 102 pharmacies) representing 86 percent of all known programs operating in California any time in the last 15 years, no survey respondents reported any signs of illegal drug diversion. Washington state's "PH:ARM Pilot" program (using a less costly two-key collection process in pharmacies than California's Model Guidelines^{§§§}) also reported no diversion incidences in the 3½ years that 39 pharmacies in their original program have been operating collection programs.⁴⁴

However, outside of these programs, one Northern California pharmacy stopped its collection program after a young woman's drug overdose death was suspected to be linked to drug diversion from the pharmacy's collection program.⁴⁵ Also, a Lynnwood, Wash., "pharmacist of the year" collected expired and unexpired drugs from doctors, hospices, clinics, and pharmacy customers to allegedly distribute to less developed countries. Instead, he filled his pharmacy's regular supply pill bottles.⁴⁶ However, this may not be considered a true "collection program" since the drug store employing the pharmacist may not have known he was collecting home-generated pharmaceutical waste from customers.⁴⁷ No other home-generated pharmaceutical waste collection program in the world is known to have illegally diverted its collected pharmaceutical waste.

STATEWIDE ACCESSIBILITY (ACCESSIBILITY)

Pharmacy program access hours ranged from five to 12 hours per day (average of nine hours per day). With approximately 6,100 pharmacies throughout California,⁴⁸ there are a very large number of possible locations for future pharmacy programs. As was shown previously in Figure 7, "Washington/Oregon Residents' Medication Disposal Preferences," 64 percent of nearly 800 consumers in Washington and Oregon would be somewhat or very likely to take their home-generated pharmaceutical waste to a "convenient" drop-off location. Nine out of 10 calls that the City of San Francisco's Toxics Reduction program receives regarding home-generated pharmaceutical waste disposal are from customers wanting to drop off their waste at pharmacies.⁴⁹ Anecdotaly, people seem to prefer the point of sale such as a pharmacy as a convenient drop-off location as opposed to household hazardous waste facilities or law enforcement stations.

§§§ The PH:ARM Pilot report [Grasso, Cheri, et al., (2009) Secure Medicine Return in Washington State, The PH:ARM Pilot. www.medicinereturn.com/resources] describes a two-key system following a less costly process: "Full boxes are removed from the container by two pharmacy staff using separate keys. After the box is taped shut, a tamper-evident seal is placed across the seams and a fax is sent to the central pharmacy warehouse notifying staff that a box of medicines will be arriving. Sealed boxes are shipped back to Bartell's central pharmacy warehouse, on the regular pharmacy route trucks. The unique numbers assigned to the boxes allow the custody and transportation to be tracked on a shipping notification form. At the central pharmacy warehouse, boxes are stored in a caged section of the warehouse until enough boxes accumulate for transportation to the disposal facility."

***** For instance, Melody LaBella with the Central Contra Costa Sanitary District and Karin North with the City of Palo Alto and current chair of the Bay Area Pollution Prevention Group have worked on home-generated pharmaceutical waste disposal issues for more than nine years each, including working with a variety of collection program types. In an Aug. 12, 2010 meeting with CalRecycle staff, each stated that people prefer point-of-sale disposal options.

COST-EFFECTIVENESS

Statewide, 75 pharmacies provided sufficient cost information to calculate the costs per pound collected. Pharmacy program costs ranged from \$1.00 to \$16.67 per pound (average of \$5.60 per pound). However, as noted above, almost all of these were not considered “model” programs. If pharmacy programs change their practices to meet the voluntary Model Guidelines, the costs could increase significantly. For example, based on written stakeholder comments after a July 20, 2010, workshop, if three specific pharmacy programs (representing 17 pharmacies) switched to the two-key system it would increase the annual costs by 141 percent (from \$30,700 to an estimated \$73,900, with an additional one-time cost of \$15,360 for bin purchases).⁵⁰

EFFICACY (COLLECTION RATE)

Statewide, 75 pharmacy programs provided sufficient information to calculate the pounds of pharmaceuticals collected. Pharmacy programs collected a total of 18,120 pounds during the survey period, corresponding to an average of 242 pounds collected per program. Pharmacy programs collected from 0.3 to 12.3 pounds per day of operation (average of 2.0 pounds per day).

QUALITATIVE SUMMARY

As presented in Figure 10, pharmacy programs:

- Excel in **accessibility** because of the large number of pharmacies in California;
- Have moderate **cost-effectiveness**;
- Have variable **efficacy** depending on the metric used; and
- Lag in **safety** because of the number of voluntary Model Guidelines criteria not met by the pharmacies.

Figure 10. Relative Strengths of Pharmacy Collection Programs

	Safety			Access			Cost	Efficacy		
	Number Models	Criteria Match	% Models	Current Sites	Hours/ Day	Possible Sites	Dollars/ Pound	Pounds/ Day	Current Pounds	Pounds/ Program
Strongest										
Medium										
Weakest										

1. The biggest strengths of pharmacy programs:
 - a. They are the point-of-sale for pharmaceuticals, so residents are familiar and comfortable with these locations.
 - b. Pharmacies are designed for public access with thousands of convenient locations throughout California, sufficient parking, and handicap-accessibility, so the expansion and convenience potentials are high.
 - c. Compared to any other program type, pharmacies have the greatest incentive to attract customers with collection programs since customers are more likely to purchase other items while there.

- d. Professionals familiar with pharmaceuticals staff the programs, so the learning curve for new programs should not be as steep.
- 2. The biggest challenges for pharmacy programs:
 - a. Each has its own unique business practices, so a one-size-fits-all model (such as the voluntary Model Guidelines) may be challenging to implement.
 - b. People associate pharmacies with drugs, so meeting some level of safety standards is even more important to prevent illegal diversion.
 - c. The public typically cannot distinguish a controlled substance from a non-controlled substance, so as long as pharmacies are not allowed to collect controlled substances without law enforcement present, this will continue to complicate pharmacy programs.
 - d. Adapting to the voluntary Model Guidelines will be difficult and expensive (especially for pre-existing programs), so acceptance and adoption of the guidelines may not be common or universal.
 - e. Collection programs may not be seen as profitable or “good for business,” so pharmacies may not commit the necessary resources and/or may be reluctant to set pharmaceutical collection as a priority.
 - f. The voluntary Model Guidelines include prescriptive security requirements for pharmacies to meet Board of Pharmacy concerns about illegal diversion. These security requirements include a costly two-key collection bin and other requirements that make it difficult for pharmacies to comply with the voluntary Model Guidelines.

LAW ENFORCEMENT PROGRAM EVALUATION

SAFETY (SECURITY)

Program Safety (Security)

While 100 percent of the 63 law enforcement programs surveyed responded that they were consistent with the Model Guidelines, CalRecycle determined that only 71 percent actually qualified as model programs. Law enforcement programs had issues with five safety-related criteria. Three issues caused most disqualifications: controlled substances (29 percent), storage times (22 percent) and hauler registration (29 percent).

Illegal Diversion Incidences

No known incidences of illegal drug diversion have occurred in any law enforcement programs. At least one diversion incident outside of a collection program was reported.⁵¹

STATEWIDE ACCESSIBILITY (ACCESSIBILITY)

Statewide, 63 existing law enforcement programs responded to the survey. Law enforcement program access hours ranged from 3 to 24 hours per day (average of 19 hours per day). Anecdotally, people may not be as familiar with the locations or accessibility of law enforcement stations and have expressed concerns about taking their pharmaceuticals to them. With approximately 900 law enforcement locations throughout California,^{††††} there are many possible sites for future law enforcement programs.

^{††††} Based on CalRecycle staff estimates from samplings of number of stations referenced here: www.road-police.com/police/california/california_police.html.

COST-EFFECTIVENESS

Statewide, each of the 63 law enforcement programs surveyed provided sufficient cost information to calculate the costs per pound collected. Law enforcement program costs ranged from \$0.38 to \$13.89 per pound (average of \$4.56 per pound).

EFFICACY (COLLECTION RATE)

Statewide, 63 law enforcement programs provided sufficient information to calculate the pounds of pharmaceuticals collected. Law enforcement programs collected a total of 194,522 pounds during the survey period, corresponding to an average of 3,088 pounds collected per program. Law enforcement programs collected from 0.1 to 34.7 pounds per day of operation (average of 7.1 pounds per day).

Law enforcement programs often have a 24-hour presence and often locate drop boxes outdoors. Some law enforcement programs reported that small businesses deposit their pharmaceutical waste, which is not considered home-generated, in these drop boxes. This inflates the amounts, increases the program disposal costs, would contradict the disposal requirements for any business generating that waste⁺⁺⁺⁺, and constitutes unfair competition for any business using this free disposal method intended only for resident use.^{§§§§}

The largest law enforcement program reported that during its initial six-month startup period (which corresponded with the CalRecycle survey period), the program suspected a large amount of business waste disposal was occurring. Additionally, the amount of pharmaceuticals collected during the six-month startup period was much higher than subsequent periods. Residents may have disposed of a large amount of stockpiled pharmaceuticals. As a result, the representativeness of the data for that program may be questionable, which could have resulted in somewhat inflated collection rates compared to long-term collection rates.

QUALITATIVE SUMMARY

As presented in Figure 11, law enforcement programs:

- Excel in **safety** by having a large percentage of model programs;
- Have moderate **accessibility** and **cost-effectiveness**; and
- Excel in program **efficacy** (although this may be due in part to suspect data).

⁺⁺⁺⁺ According to the California Medical Waste Management Act.

^{§§§§} According to Section 17200 of the California Business and Profession Code.

Figure 11. Relative Strengths of Law Enforcement Collection Programs

	Safety			Access			Cost	Efficacy		
	Number Models	Criteria Match	% Models	Current Sites	Hours/ Day	Possible Sites	Dollars/ Pound	Pounds/ Day	Current Pounds	Pounds/ Program
Strongest										
Medium										
Weakest										

1. The biggest strengths of law enforcement programs:
 - a. They are secure locations, so residents should be safe and illegal diversion should be rare.
 - b. There are nearly 1,000 locations currently in the state, so the expansion and convenience potentials are good.
 - c. Most existing programs conformed well to the voluntary Model Guidelines, so additional programs should be able to conform, too.
 - d. They can more easily meet the requirements for collecting controlled substances, so they could be convenient one-stop locations.
2. The biggest challenges for law enforcement programs:
 - a. People either think of these locations as dangerous or are unaware of their whereabouts, so getting full public participation may be difficult.
 - b. Many are facing severe budgetary and funding shortfalls, so they may not have the resources and/or may be reluctant to set pharmaceutical collection as a priority.

HHW PROGRAM EVALUATION

SAFETY (SECURITY)

Program Safety (Security)

While 78 percent of the 18 HHW programs responded that they were consistent with the Model Guidelines, CalRecycle determined that only 33 percent actually qualified as model programs. As discussed above, all of the HHW programs predated the voluntary Model Guidelines so they may have more trouble converting over to the new requirements. HHW programs had issues with three safety-related criteria. Issues related to documentation (50 percent) and storage times (44 percent) caused most disqualifications.

Illegal Diversion Incidences

No known incidences of illegal drug diversion have occurred at any household waste facilities.

STATEWIDE ACCESSIBILITY (ACCESSIBILITY)

Statewide, 18 existing HHW programs responded to the survey. HHW program access hours ranged from one to nine hours per day (average of three hours per day). With approximately 140 HHW sites throughout California, there are some additional possible locations for future HHW collection programs.

COST-EFFECTIVENESS

Statewide, 15 HHW programs provided sufficient cost information to calculate the costs per pound collected. HHW program costs ranged from \$0.13 to \$6.38 per pound (average of \$2.86 per pound). This average is considerably lower than the average costs of other programs; however, the weights of pharmaceuticals at HHW programs are more likely to be estimated rather than measured, which could impact the cost-effectiveness results (e.g., if the estimated amounts are twice the actual weight, the cost per pound will be half what it should be).

EFFICACY (COLLECTION RATE)

Statewide, 16 HHW programs provided sufficient information to calculate the pounds of pharmaceuticals collected. HHW programs collected a total of 9,349 pounds during the survey period, corresponding to an average of 584 pounds collected per program. HHW programs collected from 0.4 to 10.3 pounds per day of operation (average of 2.0 pounds per day).

QUALITATIVE SUMMARY

As presented in Figure 12, HHW programs:

- Excel in **cost-effectiveness** (although this may be due in part to suspect data);
- Have moderate **safety** and **efficacy**; and
- Lag in **accessibility** due to relatively few existing programs, few potential sites, and limited hours.

Figure 12. Relative Strengths of HHW Collection Programs

	Safety			Access			Cost	Efficacy		
	Number Models	Criteria Match	% Models	Current Sites	Hours/ Day	Possible Sites	Dollars/ Pound	Pounds/ Day	Current Pounds	Pounds/ Program
Strongest										
Medium										
Weakest										

1. The biggest strengths of HHW programs:
 - a. They are existing programs that can handle a variety of toxic materials, so they can function as one-stop locations.
 - b. Pharmaceuticals comingled with HHW represent a relatively small amount compared to all HHW and can be collected and disposed together with relative efficiency following existing practices.
2. The biggest challenges for HHW programs:
 - a. There are fewer than 150 total HHW sites in the state, so convenience and the potential for expansion is low.
 - b. Many people staff and visit HHW sites, so meeting safety standards is important to prevent illegal diversion.

- c. Many local governments that run HHW programs are facing severe budgetary and funding shortfalls, so they may not have the resources and/or be reluctant to set pharmaceutical collection as a priority.

COLLECTION EVENT EVALUATION

SAFETY (SECURITY)

Program Safety (Security)

While 76 percent of the 46 collection events responded that they were consistent with the Model Guidelines, CalRecycle determined that only 37 percent actually qualified as model programs. Collection events had issues with three safety-related criteria. Issues related to documentation (46 percent) caused most disqualifications.

Illegal Diversion Incidences

No known incidences of illegal drug diversion have occurred at any collection events.

STATEWIDE ACCESSIBILITY (ACCESSIBILITY)

Statewide, 46 existing collection events responded to the survey. Event access hours ranged from three to 12 hours per day (average of seven hours per day) when events were held. Events can be held at numerous types of locations, so there are numerous possible locations for future collection events.

COST-EFFECTIVENESS

Statewide, 36 collection events provided sufficient cost information to calculate the costs per pound collected. HHW program costs ranged from \$0.87 to \$16.67 per pound (average of \$6.06 per pound). It appears that jurisdictions with limited resources are more likely to use collection events. If costs to open and/or operate a continuous collection program are prohibitive, a jurisdiction may operate collection events to reach all residents with some level of collection service. Collection events appear to be more common in areas with large dense populations such as the City of Los Angeles or the Bay Area, and in rural jurisdictions where they provide at least some level of service to a diffuse population.

EFFICACY (COLLECTION RATE)

Statewide, 36 collection events provided sufficient information to calculate the pounds of pharmaceuticals collected. Events collected a total of 5,040 pounds during the survey period, corresponding to an average of 140 pounds collected per program. Collection events collected from 2.5 to 482.0 pounds per day of operation (average of 163.1 pounds per day). Again, these large quantities represent the amounts collected on only the days that events occurred, rather than on a daily, continuous basis.

Although events appear effective in terms of pounds collected per day, the final report for the California “No Drugs Down The Drain! Statewide Campaign, October 4-11, 2008” concluded, “While they can be successful in educating residents, event-based disposal is not a long-term solution. Some residents are not able to attend events, and stockpiling medication until a future event is not an option for many who are concerned about accidental poisoning, misuse, abuse, or diversion.”⁵²

QUALITATIVE SUMMARY

As presented in Figure 13, collection events:

- Have moderate **safety**, **accessibility**, and **cost-effectiveness**; and
- Have variable **efficacy** depending on the metric used, which should be expected for an approach that may be best at addressing specific needs in certain situations.

Figure 13. Relative Strengths of Collection Events

	Safety			Access			Cost	Efficacy		
	Number Models	Criteria Match	% Models	Current Sites	Hours/ Day	Possible Sites	Dollars/ Pound	Pounds/ Day	Current Pounds	Pounds/ Program
Strongest										
Medium										
Weakest										

1. The biggest strengths of collection events:
 - a. They are flexible and can happen in a variety of locations, so residents have reasonable access to some level of service.
 - b. They can handle large volumes of materials in a short amount of time, so they may be more effective at dealing with existing stockpiles.
 - c. Relative to other law enforcement duties, law enforcement officers may be more likely to staff a one-time event in order to collect controlled substances rather than run a full-time collection program.
 - d. They can be effective by increasing public awareness and giving stakeholders initial experience with collection issues, which may make events a potentially effective first step toward starting a continuous collection program.
2. The biggest challenges for collection events:
 - a. People may not hear about events, so without adequate publicity they may not reach the intended audiences or get full public participation.
 - b. Staffing commitments for events can be onerous and costly for the amount of pharmaceutical waste collected.
 - c. Many people staff and visit collection events, so meeting some level of safety standards may be difficult.
 - d. Many local governments that run collection events are facing severe budgetary and funding shortfalls, so they may not have the resources and/or may be reluctant to set pharmaceutical collection as a priority.

MAIL-BACK PROGRAM EVALUATION

SAFETY (SECURITY)

Program Safety (Security)

All three mail-back programs responded that they were consistent with the Model Guidelines, and CalRecycle confirmed that they all qualified as model programs. Mail-back programs had no issues with safety-related criteria. In mail-back programs, only the generator (i.e., the resident) handles pharmaceuticals and then the USPS takes custody of the envelopes, so there are very few opportunities for security issues to arise.

Illegal Drug Diversion

The following mail-back-related example of potential illegal drug diversion was not part of any official collection program. However, it does indicate the security concerns surrounding such programs even though the USPS boasts a 94 percent conviction rate for crimes that range far afield from stolen mail or forged money orders.⁵³ The USPS investigated multiple reports of prescription medication mailed to veterans from the Veterans Administration that disappeared from a South Sacramento post office.⁵⁴

STATEWIDE ACCESSIBILITY (ACCESSIBILITY)

Statewide, three existing mail-back programs responded to the survey. Mail-back access hours ranged from six to 10 hours per day (average of 8 hours per day) for mailer pickup. Mailboxes are always available, so drop-off access is essentially 24 hours per day. Pharmacies, government offices, or a variety of other locations could distribute mailers, so there are a very large number of possible distribution locations. Drop-off locations are even more plentiful with approximately 1,850 post offices and approximately 21,310 mailboxes in California.⁵⁵ Residents could even give mailers to their letter carriers. Especially for homebound residents and those in rural areas, mail-back programs allow the public to send packages at anytime at any mailbox. In terms of potential drop-off locations, mail-back programs potentially offer the greatest accessibility. Santa Cruz County's relatively small mail-back program has the highest reported return rate so far (68 percent returned/distributed), possibly because a pharmacy distributed mailers specifically to people who, for various reasons, could not use a nearby pharmaceutical drop-off site.

COST EFFECTIVENESS

Statewide, all three mail-back programs provided sufficient cost information to calculate the costs per pound collected. Mail-back costs ranged from \$4.59 to \$8.10 per pound (average of \$6.54 per pound). Because all mail-back programs started in 2009 and are relatively new in California, CalRecycle only includes the costs and pounds collected for returned mailers. Program managers pay for mailers up-front regardless of whether they are subsequently used or not. If generators (residents) do not return some mailers, then overall cost per pound will increase (e.g., if residents returned only half of the mailers, the cost per pound would double). A mailer's \$3.65 flat rate cost per envelope may encompass more upfront costs than the reported costs from pharmacy programs (e.g., staff time, kiosk cost and maintenance, and lost retail space, etc.). Finally, if residents put more pharmaceuticals in each envelope, the cost-effectiveness increases (i.e., a lower cost per pound) because the current mail-back programs use flat rate shipping arrangements. However, encouraging residents to hold onto materials longer and send fewer, fuller envelopes may increase illegal diversion opportunities. In addition, Walgreens has made postage-paid mailers available in its stores nationwide for \$2.99 each,⁵⁶ and at least 200 Kaiser Permanente

Hospitals in California are offering the same mailers for \$4.95 each.⁵⁷ Anecdotally, Kaiser has had considerable customer demand.

EFFICACY (COLLECTION RATE)

Statewide, all three mail-back programs provided sufficient information to calculate the pounds of pharmaceuticals collected. Mail-back programs collected a total of 898 pounds during the survey period, corresponding to an average of 299 pounds collected per program. Mail-back programs collected from 0.1 to 3.2 pounds per day of operation (average of 2.1 pounds per day).

QUALITATIVE SUMMARY

As presented in Figure 14, mail-back programs:

- Excel in **safety** by having 100 percent model programs;
- Have variable **accessibility** with low current accessibility but great potential accessibility;
- Have moderate **cost-effectiveness** (although this is dependent on high mailer return rates); and
- Lag in **efficacy** due to relatively few existing programs.

Figure 14. Relative Strengths of Mail-Back Collection Programs

	Safety			Access			Cost	Efficacy		
	Number Models	Criteria Match	% Models	Current Sites	Hours/ Day	Possible Sites	Dollars/ Pound	Pounds/ Day	Current Pounds	Pounds/ Program
Strongest										
Medium										
Weakest										

1. The biggest strengths of mail-back programs:
 - a. They do not require any expertise, so mailers can be distributed in a variety of ways at almost any location.
 - b. There are convenient USPS drop-off locations across California, so the potential for convenience and expansion is very high.
 - c. The costs are all paid up-front, so there are no hidden or unexpected costs to contend with.
 - d. No intermediary handles the pharmaceuticals (other than the USPS), so safety is not as much of a concern.
 - e. Fewer regulations are necessary (e.g., CDPH's policy to regulate consolidated home-generated pharmaceutical waste) since no intermediary consolidates or is considered to generate the waste.
2. The biggest challenges for mail-back programs:
 - a. There are only three programs in the state, so it may be seen by some as an unproven approach.
 - b. The costs are all paid up-front, so a very high return rate is necessary for the method to be cost-effective.

V. Potential Options and Recommendations for Further State Action

This section includes a range of potential options for further state action with regard to pharmaceutical collection programs. Options can be categorized into two groups -- regulatory and funding. Each of these is described briefly here and then in more detail below.

There are two regulatory options:

Option 1. Continue Current Use of Model Guidelines maintains the status quo and entails using voluntary federal guidelines and the current California Model Guidelines. The former teaches residents how to properly dispose of drugs in household trash if local collection programs are not available, while the California Model Guidelines address safe practices of home-generated pharmaceutical collection programs.

Option 2. Establish Clear State Agency Roles and Responsibilities, Improve Model Guidelines and Enforcement, and Convert Guidelines to Regulation relies on statutory changes to establish clear state roles and responsibilities and to provide direction to resolve several implementation challenges. It also would convert the Model Guidelines into state regulations.

These are followed by two funding options that address the need for long-term program funding, which is essential for establishing more collection programs and maintaining existing ones.

Option 3. Implement Product Stewardship with Private Sector Leadership provides program financing through a private sector approach, with government oversight. This is commonly referred to as product stewardship. Manufacturers or drug brand owners would design, manage, and finance a statewide program, while state government would oversee successful program implementation and enforcement.

Option 4. Create State Collection Program Supported by Advanced Disposal Fee relies on a fee paid by consumers at the point-of-purchase to support program activities (such fees typically are known as “advanced disposal fees”). The fees would be used to implement a state government program, in which a designated state agency would design, manage, and enforce the program, in addition to collecting and dispersing funds.

For each of these four options, CalRecycle describes in more detail below their potential impacts, arranged by the:

- Four evaluation factors specified in SB 966 (safety, accessibility, cost-effectiveness, and efficacy);
- Challenges and barriers discussed previously in this report (Expense of Safe Collection, Lack of Public Awareness and Participation, Lack of Sustainable Funding, Lack of Goals, Unclear Requirements, Policies and Authorities); and
- Environmental impacts addressed by SB 966.

Options 2, 3, and 4 would require new legislation to be implemented. At the end of this section, CalRecycle offers its recommendations for a possible combination of regulatory and financing options. CalRecycle also recognizes that there is not agreement among stakeholders on preferable types of collection programs, nor on state agency roles and responsibilities. Some stakeholders advocate that unless

federal regulations change (see Section II, 2. *National Programs*, Federal Legislation and Regulations) so that pharmacies and mail-back programs may collect controlled substances, law enforcement should collect all home-generated pharmaceuticals. Otherwise drugs would need to be sorted to follow the law, but it is hard to distinguish between a controlled and uncontrolled substance so these programs are expensive. Other stakeholders argue that mail-back programs should be the primary program type allowed because they do not face these same restrictions and because they offer convenient collection, safety, and privacy. Others argue that all collection options should be available.

1. Regulatory Options

OPTION 1. CONTINUE CURRENT USE OF MODEL GUIDELINES

Under this option the state would maintain the voluntary Model Guidelines, and where local programs do not exist, the state would encourage consumers to follow federal guidelines.

This option thus would encourage programs (such as at pharmacies and HHW facilities) to follow the Model Guidelines and allow consumers to continue to dispose of pharmaceuticals in their household trash that goes to landfills. Consequently, some pharmaceutical chemicals would likely be found in landfill leachate, although this appears to be a minor pathway for releases to the environment.*****

This option does not provide funds for public education; some other states such as New York do provide funding for education programs. If an organization (e.g., pharmaceutical manufacturers, brand owners, government) educated consumers on proper disposal, including the federal guidelines on how to dispose drugs in household trash, many of the impacts described below could be mitigated. This could be done without additional collection costs, without legislation, and result in removing unwanted drugs from households, but would not meet environmental objectives to significantly decrease pharmaceuticals released to the environment.

In contrast, if the primary concern of the Legislature is to provide convenient long-term collection opportunities for home-generated waste and to minimize illegal diversion of such waste, then other options listed in this section should be considered.

POTENTIAL IMPACTS:

Safety: No change from current level. Illegal diversion could still occur at waste disposal collection points (e.g., scavengers at trash bins, employees at materials recovery facilities). However, the “treatments”

***** CalRecycle is aware of only a few studies regarding concentrations of pharmaceuticals in leachate from U.S. landfills, and few of these are peer-reviewed. In general, they indicate that most pharmaceuticals in the environment are the result of human excretion as opposed to being from home-generated pharmaceutical waste, that pharmaceuticals may be found in generally low concentrations in landfill leachate discharged to wastewater treatment plants, and the latter could be viewed as a minor pathway by which pharmaceuticals reach the environment (see Appendix C: *Overview of Reports on Pharmaceuticals in Landfill Leachate*).

described in the federal guidelines could be adequate if consumers follow them so that drugs would be rendered non-consumable and hidden in household trash.

Accessibility: No change from current level. A wide range of collection programs could continue as they currently exist, but many consumers would remain unaware of collection options or would not participate in available programs.

Cost-effectiveness: No change from current level. This option would not reduce collection and management costs from current levels.

Efficacy: No change from current level. Collection programs could continue to explore ways of providing more cost-effective solutions without additional constraints or requirements. But this option would not significantly increase collection unless there was significant public education; as a consequence, pharmaceuticals would continue to be stored at home, disposed of in landfills, or flushed down toilets, and would eventually enter streams and groundwater. Collection levels would likely remain quite low compared to the total amount of home-generated pharmaceutical waste.

Expense of Safe Collection: No change from current challenge. Because the Model Guidelines are voluntary, some requirements would continue to be ignored in order to reduce costs.

Lack of Public Awareness and Participation: No change from current challenge. Would not address need for increased education. Greater confusion may arise if local governments adopt ordinances resulting in highly variable approaches across the state.

Lack of Sustainable Funding: No change from current challenge. Places no additional costs on state government, but would not address issue of insufficient funding or lack of sustainable funding source. Local governments would need to continue to find ways of funding these collection programs.

Lack of Goals: No change from current challenge.

Unclear Requirements, Policies and Authorities: No change from current challenge. Does not require new legislation. State agency roles and responsibilities would remain confusing and program managers would not have clear requirements to follow.

Environmental Impacts: No change from current impacts. Would not address potential impacts, such as bioaccumulation, sensitive species and/or synergistic effects, from wastewater treatment discharges (including materials originating from leachate). If excretion is the main cause of water contamination, which research supports, then this suggests a different type of approach is needed (such as designing pharmaceuticals to be better metabolized by consumers, encouraging practices that reduce over-prescribing prescriptions, and other source-reduction approaches).

OPTION 2. ESTABLISH CLEAR ROLES AND RESPONSIBILITIES, IMPROVE MODEL GUIDELINES AND CONVERT TO REGULATIONS, AND PROVIDE ENFORCEMENT AUTHORITY

This option focuses on strengthening the Model Guidelines by establishing clear state agency roles and responsibilities, making the Model Guidelines mandatory, and providing authority to enforce them.

A key element of this option is to provide clear legislative authority and “clean up” confusing laws and regulations. Appendix A: *Recommended Stakeholder Changes to Legislation, Regulations and Policies*

explores legislative alternatives for addressing several challenges facing collection programs. For example, one of the biggest points of confusion is that pharmaceutical discards can be classified and regulated in multiple ways depending on how and where they are collected and managed. The Legislature could define home-generated pharmaceutical waste and a level of management for home-generated pharmaceuticals that would provide needed safety but would be less stringent than requirements for managing medical waste. Further, the Legislature could define at what point, if any, consolidated home-generated pharmaceutical waste should be considered medical waste and handled as such. Providing needed safety would include remaining consistent with federal controlled substances laws such as the Controlled Substances Act. Legislation could also identify a state agency to develop regulations that codify current voluntary Model Guidelines and require collection and disposal programs to follow them. Additionally, the Model Guidelines could be modified to allow for additional practices, provided they offer equivalent safety (e.g., new technologies might offer lower-cost alternatives to the current two-key system used in pharmacies). The intent of these activities would be to establish clear state agency roles and responsibilities, and to improve enforcement and implementation of home-generated pharmaceutical collection and disposal programs.

As noted, under this option collection programs would be required to follow Model Guidelines to ensure safety. The Model Guidelines have been the officially sanctioned home-generated pharmaceutical waste collection guidelines in California since November 2008 and serve as a platform for establishing regulations. Additionally, out of 256 existing collection programs and events, there are not any reported signs of illegal drug diversion so it appears the Model Guidelines offer adequate safety. Legislation would have to delineate who is responsible for properly managing collected drugs and provide the lead state agency with sufficient authority to take enforcement action against non-complying entities.

Option 2 assumes no additional funding for individual collection programs would be made available, although the designated state agency would require additional resources to develop and implement regulations. Options for program funding are covered in Option 3 (private sector managed product stewardship) and Option 4 (state government managed advanced disposal fee).

POTENTIAL IMPACTS:

Safety: The percentage of programs meeting the Model Guidelines could rise if the guidelines became mandatory. However, a potential unintended result could be fewer programs, if the Model Guidelines were viewed as too onerous.

Accessibility: Because requirements will be clearer, the number of collection programs may increase to provide consumers with greater accessibility. However, the overall number of programs may not increase if the costs associated with meeting the Model Guidelines are too high. In addition, if restricted to law enforcement, accessibility would depend on the willingness of law enforcement entities to participate.

Cost-Effectiveness: Mandatory implementation of the Model Guidelines could result in higher costs and lower cost-effectiveness. If clarification of the Model Guidelines identified additional options or flexibility, costs could be reduced.

Efficacy: Some increase in collection is possible, but as long as programs are voluntary, collection levels would likely remain quite low compared to the total amount of home-generated pharmaceutical waste.

Expense of Safe Collection: Mandating use of the current Model Guidelines will likely make this challenge worse as all programs must meet all the criteria.

Lack of Public Awareness and Participation: No change from current challenge.

Lack of Sustainable Funding: Could place additional costs on state government for regulatory and enforcement activities. Would not address the issue of insufficient funding or lack of a sustainable funding source. Local governments would need to continue to find ways to fund these collection programs.

Lack of Goals: No change from current challenge.

Unclear Requirements, Policies and Authorities: Would provide an opportunity to update the Model Guidelines and set clear, consistent and enforceable standards. Could better define state agency roles and responsibilities through legislation or regulation and avoid on-going debate among state entities.

Environmental impacts: Since this option assumes no additional funding would be made available and the number of collection sites would not increase significantly, pharmaceuticals would continue to be stored at home, disposed of in landfills or flushed down toilets, and eventually enter streams and groundwater.

2. Funding Options

OPTION 3. IMPLEMENT PRODUCT STEWARDSHIP WITH PRIVATE SECTOR LEADERSHIP

Under this option, legislation would mandate a private-sector designed and managed producer responsibility approach for pharmaceuticals. This also would provide the authority for state oversight to ensure a level playing field, and address issues of state agency roles and responsibilities so that pharmaceutical collection is less confusing and more streamlined.

Because this approach is not yet used widely in California, it bears additional explanation here. Product stewardship programs use a private-sector approach to managing discards.⁵⁸ Product stewardship is a shared responsibility approach that could provide for safe, accessible, and cost-effective end-of-life management of home-generated pharmaceuticals. Product stewardship programs are working successfully in the United States, Canada, Europe, and elsewhere for products ranging from computers to paint to pharmaceuticals. In California 100 local jurisdictions have already adopted product stewardship resolutions for a variety of products, indicating growing interest and support.⁵⁹ CalRecycle has adopted a Strategic Directive on producer responsibility and adopted an Extended Producer Responsibility Framework Document in January 2008.⁶⁰ Additionally, two product stewardship laws were enacted in 2010 to establish private-sector managed and funded recycling programs for carpet (AB 2398, Perez, Chapter 681, Statutes of 2010) and architectural paint (AB 1343, Huffman, Chapter 420, Statutes of 2010).

Conceptually, this approach appropriately places the primary responsibility for pharmaceutical management with the pharmaceutical manufacturer and the consumers who use them, rather than ratepayers and local governments, which currently spend more than \$600,000 per year on what is likely a small percentage of all home-generated pharmaceutical waste.⁺⁺⁺⁺⁺ In other words, those who benefit from pharmaceuticals pay for pharmaceutical waste management costs. Using less material in the design of products, often called source reduction, prevents waste and can provide a great environmental benefit. A

⁺⁺⁺⁺⁺ A cost of \$600,000 per year is based on CalRecycle survey results from local governments (including mailback, events, and 206 continuous collection programs). Since 51 percent of all programs did not report staff time, and if current programs address only 5 percent of home-generated pharmaceuticals, then costs for collection throughout California would be much higher.

potential source reduction benefit could emerge from the closer involvement of pharmaceutical manufacturers with drug waste. Manufacturers could gain insights they currently lack regarding the extent, scope, and magnitude of drug waste and to reduce costs and negative impacts they may change their manufacturing, packaging, and prescribing/dispensing practices. For instance, pharmaceutical manufacturers may learn that certain medications intended to be taken completely are typically returned with portions unused. In this case, education practices while prescribing/dispensing may be improved in order to reduce industry-funded disposal costs. Likewise, insurers could use information gleaned from collection programs to determine optimal dispensing practices.⁶¹

Full product stewardship programs are industry-led, giving producers or manufacturers the flexibility to design and implement their own programs, with the state or federal governments' role focused on setting ground rules and providing oversight. Program costs are covered in the product price so those who use the product pay for its full cost. Producers are generally able to implement programs either individually or by joining together with other producers through a product stewardship organization that collects, properly manages, and interacts with the state oversight agency on its behalf. Product stewardship programs are financed by the private sector and government does not collect any taxes. Rather, managing materials becomes another business cost that is incorporated into product price, similar to any other costs.

Producers (or their product stewardship organization) plan and implement collection programs, and later provide for an independent audit and submit progress reports to the lead state agency. For example, the producer would select the collection system that it determines to best achieve goals for the lowest cost. It could be through a willing pharmacy, or through law enforcement, at events, through mail-back, or some combination of these. As long as goals and laws are met, state government would not be involved, except in an oversight capacity and to ensure all producers participate.

POTENTIAL IMPACTS:

Safety: An adequately funded and well coordinated, cooperative approach could result in safer handling of home-generated pharmaceutical waste. Better financing, consumer education, and more participation would likely increase the level of secure pharmaceutical management to prevent illegal diversion.

Accessibility: Would likely result in increased consumer accessibility.

Cost-Effectiveness: Creates an incentive for producers to more efficiently collect pharmaceuticals and considers product design changes that reduce management costs.

Efficacy: Private sector programs can adapt more readily to changes in laws and market conditions and modify their program to maximize effectiveness. A more comprehensive and cooperative approach could capture significantly more home-generated pharmaceutical waste.

Expense of Safe Collection: This approach may find new ways to approach the current Model Guidelines.

Lack of Public Awareness and Participation: Efforts to increase public awareness and participation would be part of the product stewardship program.

Lack of Sustainable Funding: Offers an equitable system where those who benefit from a product pay for its full costs. The option creates a new role for pharmaceutical manufacturers, who may resist additional responsibility and additional costs. It would provide sustainable funding for all program activities and could reduce financial burdens on local governments. Additional requirements on state government for oversight activities would be funded by industry through the product stewardship organization.

Lack of Goals: This option would likely have goals to work toward as part of its framework.

Unclear Requirements, Policies and Authorities: Requires new legislation that may be difficult to enact. Would minimize government bureaucracy and provide for clear government regulatory roles and responsibilities that can reduce program implementation costs.

Environmental Impacts: Less home-generated pharmaceutical waste would enter the environment. If a product stewardship program provides incentives to reduce releases into the environment, then it could help drive the creation of new and less environmentally harmful drugs. For instance, a manufacturer's share of disposal fees could be reduced proportionate to their production of pharmaceuticals that are metabolized the most and cause the least environmental impact.

OPTION 4. CREATE STATE COLLECTION PROGRAM USING ADVANCED DISPOSAL FEE AND STATE OVERSIGHT

CalRecycle already manages several programs using an advanced disposal fee (ADF). Under these programs, consumers pay a fee at the time of purchase that is deposited in a fund managed by state government. Funds from this account are used to finance a collection program as well as to support the state agency resources needed to collect fees and implement the program. CalRecycle, or another state agency, would establish the requirements for service providers participating in the collection program, certify or register service providers, pay service providers who collect the products covered under the program, and oversee compliance and enforcement.

POTENTIAL IMPACTS:

Safety: An adequately funded and well regulated program could result in safer handling of home-generated pharmaceutical waste. Better financing, consumer education, and more participation would likely increase the level of secure pharmaceutical management to prevent illegal diversion.

Accessibility: An ADF option could utilize any or all of the collection program types currently used, or could mandate more specific requirements. This option would likely result in increased consumer accessibility as more programs were created to tap into the funds collected through the ADF.

Cost-Effectiveness: There would be less incentive to be innovative or to more efficiently collect pharmaceuticals if the state requires specific method(s) and/or pays a standardized processing/collection payment to service providers. ADF programs are known to achieve high collection rates, but are expensive compared to a private sector designed and managed programs, such as those using a product stewardship approach. The approach could also increase government bureaucracy.^{****}

Efficacy: Private sector service providers would have an incentive (processing/collection payments) to create new programs and expand existing programs to gather more materials. A more comprehensive and regulated approach could capture significantly more home-generated pharmaceutical waste.

^{****} For example, California's electronic waste (e-waste) program requires approximately 75 staff across state government. Among the 20 or more e-waste programs in the country, California is the only state using an ADF approach. In part, that is because it was the first program, but since then other states have opted for a product stewardship approach, which requires fewer government resources.

Expense of Safe Collection: This approach could subsidize safe collection methods enough to make more programs feasible.

Lack of Public Awareness and Participation: Private-sector service providers would have an incentive (processing/collection payments) to educate the public about the services they provide and to compete for home-generated pharmaceutical waste.

Lack of Sustainable Funding: This option would provide sustainable funding for all program activities and place significant additional costs on state government for regulatory, fiscal, and enforcement activities funded by the ADF. It could greatly reduce burden on local governments, which currently spend more than \$600,000 per year, and would create a visible fee on consumers which may be misinterpreted as a tax. Given a fee would be tied to a specific service, it would not be a tax.

Lack of Goals: This option would likely have goals to strive for as part of its framework.

Unclear Requirements, Policies and Authorities: Requires new legislation that may be difficult to enact. Legislation would be needed to provide the authority for a state program and could result in clearer government regulatory roles and responsibilities, clearer requirements, and a more uniform approach to home-generated pharmaceutical wastes.

Environmental Impacts: Less home-generated pharmaceutical waste would enter the environment. This option would not provide an incentive to redesign pharmaceuticals to reduce their environmental impact.

3. Recommendations

Per the Legislature's direction via SB 966 that home-generated pharmaceutical programs address the safety, accessibility, cost-effectiveness, and efficacy issues, CalRecycle provides the following recommendations.

OVERALL RECOMMENDATION

To provide convenient collection opportunities for home-generated pharmaceuticals and to keep these chemicals out of landfills, CalRecycle recommends a combination of **Option 2** ("*Establish Clear State Agency Roles and Responsibilities, Improve Model Guidelines and Enforcement, and Convert Guidelines to Regulation*"), and **Option 3** ("*Implement Product Stewardship with Private Sector Leadership*") for the following reasons:

- **Provides clear state agency roles and responsibilities.** Legislation is needed to sort out roles and responsibilities because state agencies are not in a position to make these determinations on their own.
- **Clearly defines home-generated pharmaceuticals, consolidated home-generated pharmaceuticals, and acceptable management practices.** Stakeholders are confused by the various laws, regulations, and policies that may or may not exempt home-generated pharmaceuticals from requirements for medical or hazardous wastes, especially once these pharmaceuticals are consolidated. Legislation would clearly define *home-generated pharmaceutical waste* and how it shall be managed, even after it is consolidated at a collection site (e.g., as a type of medical or hazardous waste, or as its own category of waste with its own safety and transportation requirements that are more flexible than

medical waste requirements). Providing this direction and incorporating the Model Guidelines into regulations would clearly establish which practices are legal.

- **Supports safe collection, transport and management of home-generated pharmaceuticals.** These options would ensure collection programs are safe and accessible because: 1) the Model Guidelines provide for adequate safety; and 2) the product stewardship approach would provide long-term funding that encourages refining existing collection programs and establishing new ones. CalRecycle recommends that authorizing legislation should address key issues identified elsewhere in this report (see *III. Challenges and Barriers to Implementing a Model Collection Program in California*) and that the Legislature designate the state agency that develops regulations as being the same as the agency responsible for enforcement. Additionally, the Model Guidelines may become outdated over time, so the legislation should define a process for updating them, including who will make important determinations on what constitutes adequate safety for any new management practices.
- **Offers flexibility in a complex regulatory environment.** A product stewardship approach provides maximum flexibility so a program can be modified to accommodate changing laws and regulations.
- **Provides sustainable program funding.** Product stewardship provides for long-term funding using a private-sector approach without significantly growing state government.
- **Allows multiple collection systems.** Under a product stewardship approach, the producers (brand owners) would design a program to best achieve defined goals. This could include a combination of collection systems such as collection at pharmacies, law enforcement agencies, HHW facilities, events, or using mail-back or other systems that conform to public and environmental safety requirements.
- **Encourages cost-efficiency.** Because a program would be designed, managed, and paid for by the private sector, it would encourage cost-efficiency.
- **Supports key tenets of SB 966.** Options 2 and 3 have the highest potential to provide for high efficacy (collection rates), safety, statewide accessibility, and cost-effectiveness as outlined in SB 966.

However, this recommendation cannot by itself totally overcome the key barrier related to controlled substances. Since controlled substances are an important part of the home-generated pharmaceutical waste stream and regulating them is under federal authority, instituting Options 2 and 3 will be problematic for controlled substances unless federal legislation currently under consideration, or similar legislation, is passed to address this issue. Newly signed federal legislation, the *Secure and Responsible Drug Disposal Act of 2010*, (S 3397), amends the Controlled Substances Act to make it easier to collect controlled substances. Specifically, this legislation gives the federal government more flexibility in developing regulations that would allow public and private entities to operate a variety of effective and safe collection and disposal methods for controlled substances. For example, options other than law enforcement could become more readily feasible for collecting and reducing potential diversion of controlled substances. Thus, it has the potential to positively impact the ability to effectively implement Options 2 and 3, depending on the resulting regulations.

ALTERNATIVE INTERIM RECOMMENDATION

The recommendation discussed above would likely take at least a few years to implement under the best-case scenario (i.e., to enact legislation and develop the required regulations and stewardship program), yet unwanted drugs need to be removed from households now. For this reason CalRecycle offers an alternative interim recommendation. Specifically, in order to provide convenient and immediate disposal opportunities for home-generated pharmaceuticals where collection programs do not currently exist and to make these drugs less available to potential abusers, **Option 1** (“*Continue Current Use of Model Guidelines*”) could be considered for the following reasons:

- **Provides convenient, low-cost disposal.** The federal guidelines developed by the White House Office of National Drug Policy and the federal Food and Drug Administration recommend that if local collection programs are not available, expired drugs should be disposed by mixing them with an undesirable substance (e.g., coffee grounds or kitty litter), putting this mixture in an impermeable, nondescript container, and throwing the container in household trash. In basic terms this amounts to hiding the drugs in household trash. Trash disposal is available statewide, at no additional cost, making this approach convenient and low-cost disposal for consumers. This approach would accept landfills as an environmentally reasonable disposal alternative during this interim period.
- **Does not require new legislation.** Following the federal guidelines and voluntary state Model Guidelines does not require new state legislation.
- **Supports key tenets of SB 966.** While this option allows for convenient and low-cost disposal, it may fall short with respect to safety, but perhaps not more so than other options. CalRecycle is not aware of programs that offer perfect safety standards and complete protection from illegal diversion. In this case, mixing drugs with coffee grounds, for example, still renders them potentially consumable, but by placing the mixture in a nondescript container, it would be difficult for a person to know which container among thousands might have drugs. In this regard, this approach offers some safety and may be more effective than leaving expired or unwanted drugs at home or consolidating them at facilities where they can be abused or stolen. A concern to this approach is that pharmaceuticals in landfills may eventually end up in landfill leachate and enter surface and groundwater. However, available (though limited) research indicates that pharmaceutical emissions to water from landfills are generally low (see Appendix C: *Overview of Reports on Pharmaceuticals in Landfill Leachate*). This suggests that landfill disposal may be a viable alternative from an environmental benefit perspective.

The Legislature may consider that, in the short-term, public safety may be best served by encouraging landfill disposal in communities where no other options currently exist. For example, Option 1 could be implemented as a short-term solution, while efforts to implement Options 2 and 3 proceed, given that it would take time to enact authorizing legislation and develop and implement regulations. If this approach is used, it should be re-evaluated periodically because new laws and regulations may allow for easier collection of home-generated pharmaceuticals and this may allow other options to be implemented at a lower cost and more quickly.

V. Source Reference Notes

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